COLORADO
Department of Health Care Policy & Financing

Health First COLORADO
Colorado's Medicaid Program

Colorado Department of Health Care Policy and Financing
Preferred Drug List (PDL)
Effective January 1, 2022

PA Forms: Available online at https://www.colorado.gov/hcpf/pharmacy-resources
PA Requests: Colorado Pharmacy Call Center Phone Number: 800-424-5725 | Colorado Pharmacy Call Center Fax Number: 800-424-5881
The PDL applies to Medicaid fee-for-service members. It does not apply to members enrolled in Rocky Mountain Health HMO or Denver Health Medicaid Choice.

Initiation of pharmaceutical product subject to Prior Authorization:
Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.

Health First Colorado, at 25.5-5-501, requires the generic of a brand name drug be prescribed if the generic is therapeutically equivalent to the brand name drug. Exceptions to this rule are: 1) If the brand name drug is more cost effective than the generic as determined by the Department, 2) If the patient has been stabilized on a brand name drug and the prescriber believes that transition to a generic would disrupt care, and 3) If the drug is being used for treatment of mental illness, cancer, epilepsy, or human immunodeficiency virus and acquired immune deficiency syndrome.
Please see the **Brand Favored Product List** for a list of medications where the brand name drug is more cost effective than the generic drug.

Brand Name Required = BNR, Prior Authorization = PA, AutoPA = authorization can be automated at the point of sale transaction if criteria are met
Preferred drug list applies only to prescription (RX) products, unless specified

Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred products will be approved for one year unless otherwise stated.)
I. Analgesics		
Therapeutic Drug Class: **NON-OPIOID ANALGESIA AGENTS - Oral** - *Effective 7/1/2021*		
No PA Required Duloxetine capsule (generic Cymbalta) Gabapentin capsule, tablet, solution Pregabalin capsule	**PA Required** CYMBALTA (duloxetine) capsule DRIZALMA (duloxetine DR) sprinkle capsules Duloxetine capsule (generic Irenka) GRALISE (gabapentin ER) HORIZANT (gabapentin ER) tablet	Non-preferred oral non-opioid analgesic agents may be approved if member meets all of the following criteria: ● Member has trialed and failed duloxetine (20mg, 30mg, or 60mg) AND has trialed and failed gabapentin OR pregabalin capsule (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction) Prior authorization will be required for Lyrica (pregabalin) capsule dosages > 600mg per day (maximum of 3 capsules daily) and gabapentin dosages > 3600mg per day.

SAVELLA (milnacipran) tablet, titration pack	LYRICA (pregabalin) capsule, solution, CR tablet NEURONTIN (gabapentin) capsule, tablet, solution Pregabalin solution	
Therapeutic Drug Class: **NON-OPIOID ANALGESIA AGENTS - Topical** - *Effective 7/1/2021*		
No PA Required *Brand/generic changes effective 1/1/2022* LIDODERM[BNR] (lidocaine) patch	**PA Required** Lidocaine patch ZTLIDO (lidocaine) topical system	Non-preferred topical products require a trial/failure with an adequate 8-week trial of gabapentin AND pregabalin AND duloxetine AND lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction. Prior authorization will be required for lidocaine patch quantities exceeding 90 patches per 30 days (maximum of 3 patches daily).
Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Oral** - *Effective 1/1/2022*		
No PA Required Celecoxib capsule Diclofenac potassium tablet Diclofenac sodium EC/DR tablet Ibuprofen suspension, tablet (RX) Indomethacin capsule, ER capsule Ketorolac tablet** Meloxicam tablet Nabumetone tablet Naproxen DR/ER, tablet (RX) Naproxen EC* tablet (RX) *(all manufacturers except *Woodward)* Naproxen suspension* *(all manufacturers except *Acella)*	**PA Required** ARTHROTEC (diclofenac sodium/ misoprostol) tablet CELEBREX (celecoxib) capsule DAYPRO (oxaprozin) caplet Diclofenac sodium ER tablets Diclofenac sodium/misoprostol tablet Diflunisal tablet DUEXIS (ibuprofen/famotidine) tablet Etodolac capsule, IR and ER tablet FELDENE (piroxicam) capsule Fenoprofen capsule, tablet Flurbiprofen tablet Ibuprofen/famotidine tablet INDOCIN (indomethacin) susp	**DUEXIS (ibuprofen/famotidine)** or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria: • Trial and failure‡ of all preferred NSAIDs at maximally tolerated doses **AND** • Trial and failure‡ of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND** • Has a documented history of gastrointestinal bleeding All other non-preferred oral agents may be approved following trial and failure‡ of four preferred agents. ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. **Ketorolac tablets quantity limitations: 5-day supply per 30 days and 20 tablets per 30 days

Sulindac tablet	Ketoprofen IR, ER capsule Meclofenamate capsule Mefenamic acid capsule Meloxicam suspension Meloxicam (submicronized) capsule MOBIC (meloxicam) tablet NALFON (fenoprofen) capsule, tablet NAPRELAN (naproxen CR) tablet Naproxen EC tablet (*Woodward only*) Naproxen suspension (*Acella only*) Naproxen sodium CR, ER, IR tablet Naproxen/esomeprazole DR tablet Oxaprozin tablet Piroxicam capsule QMIIZ (meloxicam) ODT RELAFEN DS (nabumetone) tablet Tolmetin tablet, capsule VIMOVO (naproxen/esomeprazole) DR tablet VIVLODEX (meloxicam, submicronized) capsule ZIPSOR (diclofenac potassium) capsule ZORVOLEX (diclofenac, submicronized) capsule	
Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Non-Oral -** *Effective 1/1/2022*		
No PA Required	**PA Required**	**SPRIX (ketorolac)** may be approved if meeting the following criteria:

Diclofenac 1.5% topical solution VOLTAREN (diclofenac) 1% gel (Rx) Diclofenac sodium 1% (generic Voltaren) gel (Rx)	Diclofenac 1.3% topical patch (generic Flector) FLECTOR (diclofenac) 1.3% topical patch Ketorolac nasal spray LICART (diclofenac) 1.3% topical patch PENNSAID (diclofenac solution) 2% Pump SPRIX (ketorolac) nasal spray	• Member is unable to tolerate, swallow or absorb oral NSAID formulations **OR** • Member has trialed and failed three preferred oral or topical NSAID agents (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) • Quantity limit: 5-single day nasal spray bottles per 30 days All other non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **FLECTOR (diclofenac)** patch quantity limit: 2 patches per day Diclofenac 3% gel (generic Solaraze) prior authorization criteria can be found in the Antineoplastic agents, topical, section of the PDL.

Opioid Utilization Policy (long-acting and short-acting opioids):

It is highly encouraged that the healthcare team utilize the Prescription Drug Monitoring Program (PDMP) to aid in ensuring safe and efficacious therapy for members using controlled substances.

Total Morphine Milligram Equivalent Policy Effective 10/1/17:

- The maximum allowable morphine milligram equivalent (MME) is 200 MME. Prescriptions for short-acting (SA) and long-acting (LA) opioids are cumulatively included in this calculation. The prescription that exceeds the cumulative MME limit of 200 MME for a member will require prior authorization and may require a provider-to-provider telephone consultation with the pain management physician (free of charge and provided by Health First Colorado).
- Prior authorization will be granted to allow for tapering
- Prior authorization for 1 year will be granted for diagnosis of sickle cell anemia
- Prior authorization for 1 year will be granted for admission to or diagnosis of hospice or end of life care
- Prior authorization for 1 year will be granted for pain associated with cancer

MME calculation is conducted using conversion factors from the following website: http://agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm

Only one long-acting opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Medicaid provides guidance on the treatment of pain, including tapering, on our webpage under the heading Pain Management Resources and Opioid Use at: https://www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use

Opioid Naïve Policy Effective 8/1/17 (*Update effective 11/27/19 in Italics*):
Members who have not filled a prescription for an opioid within the past 180 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s):

- The prescription is limited to short-acting opioid agents *or Butrans (buprenorphine) 5mcg patch*. *Use of other* long-acting opioid agents will require prior authorization approval for members identified as opioid treatment naïve.
- The days' supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7-day supply
- The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a clinical pharmacist review or provider to provider telephone consultation with a pain management physician (free of charge and provided by Health First Colorado).

- If a member has had an opioid prescription filled within the past 180 days, then this policy would not apply to that member and other opioid policies would apply as applicable.

Dental Prescriptions Opioid Policy Effective 11/15/18 (implemented in the claims system 01/07/19):
Members who receive an opioid prescribed by a dental provider will be subject to day supply limits and quantity per day limits for short acting opioids.

- The prescription is limited to short-acting opioid agents only. Use of long-acting opioid agents and short acting fentanyl agents will require prior authorization approval for members' prescriptions written by a dental provider.
- The days' supply of the first, second, and third prescription for an opioid will be limited to 4 days, the quantity will be limited to 6 dosage forms per day (tablets, capsules), maximum #24 tablets/capsules for a 4-day supply
- The fourth prescription for an opioid will require prior authorization. A prior authorization for the fourth fill may be approved for up to a 7-day supply and the quantity will be limited to 8 dosage forms per day (#56 tablets/capsules) for members with any of the following diagnoses/undergoing any of the following procedures:
    - Traumatic oro-facial tissue injury with major mandibular/maxillary surgical procedures
    - Severe cellulitis of facial planes
    - Severely impacted teeth with facial space infection necessitating surgical management
- Other potential exemptions that exceed the first 3 fill limits (day supply and quantity) may be evaluated with a provider-to-provider telephone consult with a pain management specialist (free of charge and provided by Health First Colorado)

If a member has had an opioid prescription prescribed by a non-dental provider, then this policy would not apply to that member and other opioid policies would apply as applicable. Dental prescriptions do not impact the opioid treatment naïve policy, but the prescriptions will be counted towards the Morphine Milligram Equivalent (MME) daily dose.

Opioid and Benzodiazepine Combination Effective 9/15/19:
Prior authorization will be required for members receiving long-term therapy with an opioid medication who are newly started on a benzodiazepine medication OR for members receiving long-term therapy with a benzodiazepine medication who are newly started on an opioid medication. Prior authorization may be approved if meeting the following:

- The member discontinued or is no longer taking either the opioid or benzodiazepine medication and will not be using these in combination **OR**
- The member will not be taking the prescribed opioid and benzodiazepine medications at the same time based on prescribed dosing interval (such as prn administration) for the regimen AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**
- The prescriber has evaluated the regimen and attests that it is appropriate for the member to continue use of the concomitant opioid and benzodiazepine medication regimen as prescribed AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**
- Prior authorization may be approved for members receiving palliative or hospice care **OR**
- For benzodiazepine prior authorizations, approval may be granted if the benzodiazepine is being prescribed for seizure disorder or convulsions.

**If counseling has not been provided, the prescriber attests that a reasonable effort will be made to contact the member or the member's pharmacy to ensure that counseling is provided.*

Opioid and Quetiapine Combination Effective 9/15/19:
Pharmacy claims for members receiving opioid and quetiapine medications in combination will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) related to risk of increased sedation from concomitant use of this drug combination.

Opioid and Buprenorphine-Containing substance use disorder (SUD) Product Combination Effective 06/01/21:

Opioid claims submitted for members currently receiving buprenorphine-containing SUD medications will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) with use of this drug combination.

Therapeutic Drug Class: **OPIOIDS, Short Acting** - *Effective 7/1/2021*

No PA Required* **(if criteria and quantity limit is met)**	**PA Required**	*Preferred codeine and tramadol products do not require prior authorization for adult members (18 years of age or greater) if meeting all other opioid policy criteria. Preferred codeine or tramadol products prescribed for members < 18 years of age must meet the following criteria:
Acetaminophen/codeine tablets*	Acetaminophen / codeine elixir	• **Preferred tramadol and tramadol-containing products** may be approved for members < 18 years of age if meeting the following: o Member is 12 years to 17 years of age **AND** o Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member is not obese (BMI-for-age > 95th percentile per CDC guidelines) and does not have obstructive sleep apnea or severe lung disease OR o For members < 12 years of age with complex conditions or life-limiting illness who are receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis
Hydrocodone/acetaminophen solution, tablet	APADAZ (benzhydrocodone/ acetaminophen)	
Hydromorphone tablet	ASCOMP WITH CODEINE (codeine/ butalbital/aspirin/caffeine)	
Morphine IR solution, tablet	Benzhydrocodone/acetaminophen	
Oxycodone solution, tablet	Butalbital/caffeine/acetaminophen/ codeine* capsule	
Oxycodone/acetaminophen tablet	Butalbital/caffeine/aspirin/codeine capsule	
Tramadol 50mg*	Butalbital compound w/ codeine	• **Preferred Codeine and codeine-containing products** will receive prior authorization approval for members meeting the following criteria may be approved for members < 18 years of age if meeting the following: o Member is12 years to 17 years of age AND o Codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member is not obese (BMI-for-age > 95th percentile per CDC guidelines) and does not have obstructive sleep apnea or severe lung disease AND o Member is not pregnant or breastfeeding AND o Renal function is not impaired (GFR > 50 ml/min) AND o Member is not receiving strong inhibitors of CYP3A4 (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle) AND o Member meets <u>one</u> of the following: • Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine • Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: "Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy."
Tramadol/acetaminophen tablet*	Butorphanol tartrate (nasal) spray	
	Carisoprodol/aspirin/codeine	
	Codeine tablet	
	DILAUDID (hydromorphone) (all forms)	
	FIORICET/CODEINE (codeine/ butalbital/acetaminophen/caffeine) capsule	
	FIORINAL/CODEINE (codeine/ butalbital/aspirin/caffeine) capsule	
	Hydrocodone/ibuprofen tablet	
	Hydromorphone solution	
	Levorphanol tablet	
	LORTAB (hydrocodone/acetaminophen) elixir, tablet	
	Meperidine solution, tablet	

	Morphine concentrated solution, oral syringe NALOCET (oxycodone/ acetaminophen) NORCO (hydrocodone/acetaminophen) NUCYNTA** (tapentadol) tablet OXAYDO (oxycodone) tablet Oxycodone/aspirin tablet Oxycodone/ibuprofen tablet Oxycodone capsule, syringe, conc solution Oxymorphone tablet Pentazocine/naloxone tablet PERCOCET (oxycodone/ acetaminophen) tablet ROXICODONE (oxycodone) tablet ROXYBOND (oxycodone) tablet Tramadol 100mg tablet ULTRACET (tramadol/ acetaminophen) ULTRAM (tramadol)	****Nucynta® IR** (tapentadol) may be approved for members who meet the following criteria: ● Member has history of trial/failure of 7-days utilization of preferred product(s)in the last 21 days OR ● If member does not meet the above criteria, prior authorization approval for Nucynta IR will require trial and failure of three preferred agents. Failure is defined as lack of efficacy, intolerable side effects, significant drug-drug interaction, allergy‡, or significant adverse drug reaction. ● Nucynta IR will have a maximum daily quantity of 6 tablets (180 tabs per 30 days). Non-preferred tramadol products may be approved following trial and failure of generic tramadol 50mg tablet AND generic tramadol/acetaminophen tablet. All other non-preferred short-acting opioid products may be approved following trial and failure of three preferred products. Failure is defined as allergy‡, lack of efficacy, intolerable side effects, or significant drug-drug interaction. ‡Allergy: hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema <u>Quantity Limits</u>: Short-acting opioids will be limited to a total of 120 tablets per 30 days (4/day) per member for members who are not included in the opioid treatment naive policy. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident). <u>Maximum Doses:</u> Tramadol: 400mg/day Codeine: 360mg/day Butorphanol intranasal: 10ml per 30 days (four 2.5ml 10mg/ml package units per 30 days)
Therapeutic Drug Class: **FENTANYL PREPARATIONS (buccal, intranasal, transmucosal, sublingual) -** *Effective 7/1/2021*		
	PA Required ABSTRAL (fentanyl citrate) SL tablet ACTIQ (fentanyl citrate) lozenge Fentanyl citrate lozenge, buccal tablet	Fentanyl buccal, intranasal, transmucosal, and sublingual products: Prior authorization approval may be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The prior authorization may be granted for up to 4 doses per day. For patients in hospice or

	FENTORA (fentanyl citrate) buccal tablet	palliative care, prior authorization will be automatically granted regardless of the number of doses prescribed.
Therapeutic Drug Class: **OPIOIDS, Long Acting -** *Effective 7/1/2021*		
No PA Required (*if dose met) BUTRANS[BNR] (buprenorphine) transdermal patch *Fentanyl 12mcg, 25mcg, 50mcg, 75mcg, 100mcg transdermal patch Morphine ER (generic MS Contin) tablet Tramadol ER (generic Ultram ER) tablet	**PA Required** *NUCYNTA ER (tapentadol ER) *OXYCONTIN (oxycodone ER) tablet BELBUCA (buprenorphine) buccal film Buprenorphine transdermal patch CONZIP (tramadol ER) capsule Fentanyl 37mcg, 62mcg, 87mcg transdermal patch Hydrocodone ER capsule, tablet Hydromorphone ER tablet HYSINGLA (hydrocodone ER) tablet KADIAN (morphine ER) capsule Methadone (all forms) MORPHABOND (morphine ER) tablet Morphine ER capsules MS CONTIN (morphine ER) tablet Oxycodone ER tablet Oxymorphone ER tablet Tramadol ER (generic Ryzolt/Conzip) XTAMPZA ER (oxycodone) capsule ZOHYDRO ER (hydrocodone) capsule	*__Nucynta ER__ or __Oxycontin__ may be approved for members who have trialed and failed‡ treatment with TWO preferred agents. All other non-preferred products may be approved for members who have trialed and failed‡ three preferred products. ‡Failure is defined as lack of efficacy with 14-day trial due to allergy (hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema), intolerable side effects, or significant drug-drug interaction. Methadone: Members may receive 30-day approval when prescribed for neonatal abstinence syndrome without requiring trial and failure of preferred agents or opioid prescriber consultation. Methadone Continuation: Members who have been receiving methadone for pain indications do not have to meet non-preferred criteria. All new starts for methadone will require prior authorization under the non-preferred criteria listed above. *If a prescriber would like to discuss strategies for tapering off methadone or transitioning to other pain management therapies for a Health First Colorado member, consultation with the Health First Colorado pain management physician is available free of charge by contacting the pharmacy call center helpdesk and requesting an opioid prescriber consult.* Reauthorization: Reauthorization for a non-preferred agent may be approved if the following criteria are met: ● Provider attests to continued benefit outweighing risk of opioid medication use AND ● Member met original prior authorization criteria for this drug class at time of original authorization Quantity/Dosing Limits: ● **Oxycontin, Opana ER, Nucynta ER,** and **Zohydro ER** will only be approved for twice daily dosing. ● **Hysingla ER** will only be approved for once daily dosing.

		• **Fentanyl patches** will require a PA for doses of more than 15 patches/30 days (if using one strength) or 30 patches for 30 days (if using two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr, member must trial and fail two preferred strengths of separate patches that will provide the desired dose (such as 12mcg/hr + 50mcg/hr = 62mcg/hr).

II. Anti-Infectives

Therapeutic Drug Class: **ANTIBIOTICS, INHALED** -*Effective 1/1/2022*

No PA Required (*Must meet eligibility criteria)	**PA Required**	
Tobramycin inhalation solution (generic TOBI) *CAYSTON (aztreonam) inhalation solution	ARIKAYCE (amikacin liposomal) inhalation vial BETHKIS (tobramycin) inhalation ampule KITABIS (tobramycin) nebulizer pak TOBI (tobramycin) inhalation solution TOBI PODHALER (tobramycin) inhalation capsule Tobramycin inhalation ampule (generic Bethkis) Tobramycin nebulizer pak (generic Kitabis)	*__CAYSTON (aztreonam)__ inhalation solution may be approved if the following criteria are met: • Member has a history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, intolerable side effects, or significant drug-drug interactions) **OR** provider attests that member cannot use preferred tobramycin solution for inhalation due to documented allergy or contraindication to therapy **AND** • The member has known colonization of *Pseudomonas aeruginosa* in the lungs **AND** • The member has been prescribed an inhaled beta agonist to use prior to nebulization of Cayston (aztreonam). **ARIKAYCE (amikacin)** may be approved if the following criteria are met: • Member has refractory mycobacterium avium complex (MAC) lung disease with limited or no alternative treatment options available **AND** • Member has trialed and failed 6 months of therapy with a 3-drug regimen that includes a macrolide (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions). All other non-preferred inhaled antibiotic agents may be approved if the following criteria are met: • The member has a diagnosis of cystic fibrosis with known colonization of *Pseudomonas aeruginosa* in the lungs **AND** • Member has history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).

Table 1: Minimum Age, Maximum Dose, and Quantity Limitations

	Minimum Age	**Maximum Dose**	**Quantity Limit (based on day supply limitation for pack size dispensed)**
ARIKAYCE (amikacin)	≥ 18 years	590 mg daily	Not applicable

BETHKIS (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
CAYSTON (aztreonam)	≥ 7 years	225 mg daily	28-day supply per 56-day period
KITABIS PAK (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI † (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI PODHALER (tobramycin)	Age ≥ 6 years	112 mg twice daily	28-day supply per 56-day period
† Limitations apply to brand product formulation only			

Members currently stabilized on any inhaled antibiotic agent in this class may receive approval to continue on that agent.

Therapeutic Drug Class: **ANTI-HERPETIC AGENTS - Oral -***Effective 1/1/2022*

No PA Required	**PA Required**
Acyclovir tablet, capsule	Acyclovir suspension *(members over 5)*
Acyclovir suspension *(members under 5 years or with a feeding tube)*	SITAVIG (acyclovir) buccal tablet
	VALTREX (valacyclovir) tablet
Famciclovir tablet	ZOVIRAX (acyclovir) suspension
Valacyclovir tablet	

Non-preferred products may be approved for members who have failed an adequate trial with two preferred products with different active ingredients. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

Sitavig (acyclovir) buccal tablet may be approved for diagnosis of recurrent herpes labialis (cold sores) if member meets non-preferred criteria listed above AND has failed trial with oral acyclovir suspension. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members with a diagnosis of Bell's palsy, valacyclovir 1000 mg three times daily may be approved for 7 days if member presents with severe facial palsy.

Acyclovir suspension may be approved for:
- Members under 5 years of age OR
- Members with a feeding tube OR
- Members meeting non-preferred criteria listed above.

Maximum Dose Table		
	Adult	**Pediatric**
Acyclovir	4000 mg daily	3200 mg daily
Valacyclovir	4000 mg daily	Age 2-11 years: 3000mg daily Age ≥ 12 years: 4000mg daily

<table>
<tr><th colspan="3">Therapeutic Drug Class: ANTI-HERPETIC AGENTS- Topical - Effective 1/1/2022</th></tr>
<tr><td>No PA Required

Acyclovir ointment

DENAVIR (penciclovir) cream

ZOVIRAXBNR (acyclovir) cream</td><td>PA Required

Acyclovir cream

XERESE (acyclovir/ hydrocortisone) cream

ZOVIRAX (acyclovir) ointment</td><td>Non-Preferred Zovirax and acyclovir ointment/cream formulations may be approved for members who have failed an adequate trial with the preferred topical acyclovir ointment/cream product (diagnosis, dose and duration) as deemed by approved compendium. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Xerese (acyclovir/hydrocortisone) prior authorization may be approved for members that meet the following criteria:
● Documented diagnosis of recurrent herpes labialis AND
● Member is immunocompetent AND
● Member has failed treatment of at least 10 days with acyclovir (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND
● Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 grams twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)</td></tr>
<tr><th colspan="3">Therapeutic Drug Class: FLUOROQUINOLONES – Oral -Effective 1/1/2022</th></tr>
<tr><td>No PA Required
(*if meeting eligibility criteria)

*CIPRO (ciprofloxacin) oral suspension

*Ciprofloxacin oral suspension

Ciprofloxacin tablet

Levofloxacin tablet</td><td>PA Required

BAXDELA (delafloxacin) tablet

CIPRO (ciprofloxacin) tablet

Ciprofloxacin ER tablet

Levofloxacin oral solution

Moxifloxacin tablet

Ofloxacin tablet</td><td>*CIPRO (ciprofloxacin) suspension may be approved for members < 5 years of age without prior authorization. For members ≥ 5 years of age, CIPRO (ciprofloxacin) suspension may be approved for members who cannot swallow a whole or crushed tablet.

Non-preferred products may be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Levofloxacin solution may be approved for members < 5 years of age with prescriber attestation that member is unable to take Cipro (ciprofloxacin) crushed tablet or suspension OR for members < 5 years of age for treatment of pneumonia.
For members ≥ 5 years of age, levofloxacin solution may be approved for members who require administration via feeding tube OR who have failed an adequate trial (7 days) of ciprofloxacin suspension. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy.</td></tr>
<tr><th colspan="3">Therapeutic Drug Class: HEPATITIS C VIRUS TREATMENTS - Effective 1/1/2022</th></tr>
<tr><th colspan="3">Direct Acting Antivirals (DAAs)</th></tr>
<tr><td colspan="2">PA Required for all agents in this class
Prior authorization requests must be submitted via the Hepatitis C Prior Authorization Request Form link on the Pharmacy Resources page:
https://www.colorado.gov/hcpf/pharmacy-resources</td><td><table><tr><th colspan="2">Preferred Hepatitis C Virus Treatment Regimens</th></tr><tr><td>Harvoni tablet/pellet
(ledipasvir/sofosbuvir)</td><td>May be approved for members 3 years and older for GT 1, 4-6 who are NC, have CC; or GT 1 in combination with ribavirin in DC; or</td></tr></table></td></tr>
</table>

EPCLUSA (sofosbuvir/velpatasvir) 200 mg -50 mg, 150 mg-37.5 mg tablet, pellet pack HARVONI (ledipasvir/sofosbuvir) 45mg-200mg tablet, pellet pack Ledipasvir/Sofosbuvir 90 mg-400 mg tablet (*Asequa only)* MAVYRET (glecaprevir/pibrentasvir) tablet, pellet pack Sofosbuvir/Velpatasvir 400mg-100mg (*Asequa only)* VOSEVI [2nd Line] tablet (sofosbuvir/velpatasvir/voxilaprevir)	EPCLUSA 400 mg-100 mg (sofosbuvir/velpatasvir) tablet HARVONI 90 mg-400 mg (ledipasvir/sofosbuvir) tablet SOVALDI (sofosbuvir) tablet, pellet packet VIEKIRA PAK (ombitasvir/paritaprevir/ritonavir/dasabuvir) tablet ZEPATIER (elbasvir/grazoprevir) tablet

	GT 1,4 in combination with ribavirin for liver transplant recipients who are NC, have CC; AND meet the below applicable criteria. Harvoni pellet may be approved for members 3 years of age or older weighing less than 17 kg or members 3 years of age or older that are unable to take/swallow ledipasvir/sofosbuvir oral tablets; AND meet the below applicable criteria.
Mavyret tablet (glecaprevir/pibrentasvir)	May be approved for members 3 years and older for GT 1-6 who are NC or have CC (Child-Pugh A), OR for members 3 years and older with GT 1 who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both; AND meet the applicable criteria below regarding initial treatment or re-treatment.
Epclusa tablet/pellet (sofosbuvir/velpatasvir)	May be approved for members 3 years and older or weighing at least 17 kg for GT 1-6 who are NC, have CC (Child-Pugh A); or in combination with ribavirin in DC; AND meet the applicable criteria below regarding initial treatment or retreatment. Epclusa pellet may be approved for members ≥ 3 years of age weighing less than 17 kg or members 3 years of age or older that are unable to take/swallow ledipasvir/sofosbuvir oral tablets; AND meet the applicable criteria below regarding initial treatment or retreatment.
Vosevi tablet[2nd Line] (sofosbuvir/velpatasvir/voxilaprevir)	May be approved for members 18 years or older with chronic HCV infection who are NC, have CC (Child-Pugh A) AND meet one of the following: • GT 1-6 and has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) OR • GT 1a or 3 and has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor AND meet the applicable criteria below for re-treatment.

(GT-Genotype, NC-Non-Cirrhotic, CC-Compensated Cirrhosis, DC-Decompensated Cirrhosis)

Initial Treatment (all agents):

Preferred agents may be approved for initial treatment if the following criteria are met:

- HCV treatment is being prescribed either through consultation with an expert in hepatitis C treatment OR the primary care provider attests to having received sufficient education to safely prescribe the listed hepatitis C medications **AND**
- Prescriber attests that the member has been counseled about the importance of adherence to initial therapy to treat hepatitis C **AND**
- Physician attests to meeting <u>one</u> of the following:
    - Member has a diagnosis of chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) OR
    - Member has a diagnosis of acute HCV infection in the setting of solid organ transplant OR

		○ Prescriber wishes to treat a member with acute HCV infection upon initial diagnosis and acknowledges that the rate of spontaneous resolution of acute infection has been considered as part of assessing the need to initiate antiviral therapy (acute HCV infection may spontaneously clear in 20-50% of patients) All other non-preferred agents may be approved if the criteria for initial treatment above are satisfied **AND** documentation is provided indicating an acceptable rationale for not prescribing a preferred treatment regimen (acceptable rationale may include patient-specific medical contraindications to a preferred treatment or cases where a member has initiated treatment on a non-preferred drug and needs to complete therapy). **Re-treatment:** All requests for HCV re-treatment for members who have failed therapy with a DAA will be reviewed on a case-by-case basis. Additional information will be requested for retreatment requests including (but not limited to): • Previous regimen medications and dates treated • Genotype of previous HCV infection • Any information regarding adherence to previously trialed regimen(s) and current chronic medications • Adverse effects experienced from previous treatment regimen • Concomitant therapies during previous treatment regimen • Vosevi regimens will require verification that member has been tested for evidence of active hepatitis B virus (HBV) infection and for evidence of prior HBV infection prior to initiating treatment. Members currently receiving treatment with a non-preferred agent will receive approval to finish their treatment regimen, provided required documentation is sent via normal PAR process.
Ribavirin Products		
No PA Required Ribavirin capsule Ribavirin tablet	**PA Required** RIBASPHERE (ribavirin) tablet, dosepack	Non-preferred ribavirin products require prior authorizations which will be evaluated on a case-by-case basis.
Therapeutic Drug Class: **HUMAN IMMUNODEFICIENCY VIRUS (HIV) TREATMENTS, ORAL -** *Effective 1/1/2022* **Effective 01/14/22, oral products indicated for HIV pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.**		
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
No PA Required	**PA Required**	All products are preferred and do not require prior authorization.

EDURANT (rilpivirine) tablet Efavirenz capsule, tablet Etravirine tablet INTELENCE (etravirine) tablet Nevirapine suspension, IR tablet, ER tablet PIFELTRO (doravirine) tablet SUSTIVA (efavirenz) capsule, tablet VIRAMUNE (nevirapine) suspension VIRAMUNE XR (nevirapine ER) tablet		
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)		
No PA Required Abacavir solution, tablet Didanosine DR capsule Emtricitabine capsule EMTRIVA (emtricitabine) capsule, solution EPIVIR (lamivudine) solution, tablet Lamivudine solution, tablet RETROVIR (zidovudine) capsule, syrup Stavudine capsule, solution Tenofovir disoproxil fumarate (TDF) tablet VIREAD (TDF) oral powder, tablet ZIAGEN (abacavir) solution, tablet Zidovudine capsule, syrup, tablet TDF – Tenofovir disoproxil fumarate	**PA Required**	All products are preferred and do not require prior authorization.
Protease Inhibitors (PIs)		

No PA Required	PA Required	All products are preferred and do not require prior authorization.
APTIVUS (tipranavir) capsule Atazanavir capsule CRIXIVAN (indinavir) capsule Fosamprenavir tablet INVIRASE (saquinavir) tablet LEXIVA (fosamprenavir) suspension, tablet NORVIR (ritonavir) powder packet, solution, tablet PREZISTA (darunavir) suspension, tablet REYATAZ (atazanavir) capsule, powder pack Ritonavir tablet VIRACEPT (nelfinavir) tablet		
Other Agents		
No PA Required	**PA Required**	All products are preferred and do not require prior authorization.
ISENTRESS (raltegravir) chewable, powder pack, tablet ISENTRESS HD (raltegravir) tablet RUKOBIA (fostemsavir tromethamine ER) tablet SELZENTRY (maraviroc) solution, tablet TIVICAY (dolutegravir) tablet TIVICAY PD (dolutegravir) tablet for suspension TYBOST (cobicistat) tablet VOCABRIA (cabotegravir) tablet		
Combination Agents		
No PA Required*	**PA Required**	All products are preferred and do not require prior authorization.

Dispense as written (DAW) should be indicated on the prescription Abacavir/Lamivudine tablet Abacavir/Lamivudine/Zidovudine tablet ATRIPLA (efavirenz/emtricitabine/TDF) tablet BIKTARVY (bictegravir/emtricitabine/TAF) tablet CIMDUO (lamivudine/TDF) tablet COMBIVIR (lamivudine/zidovudine) tablet COMPLERA (emtricitabine/rilpivirine/TDF) tablet DELSTRIGO (doravirine/lamivudine/TDF) tablet DESCOVY (emtricitabine/TAF) tablet DOVATO (dolutegravir/lamivudine) tablet Efavirenz/Emtricitabine/TDF tablet Efavirenz/Lamivudine/TDF tablet Emtricitabine/TDF tablet EPZICOM (abacavir/lamivudine) tablet EVOTAZ (atazanavir/cobicistat) tablet GENVOYA (elvitegravir/cobicistat/emtricitabine/TAF) tablet JULUCA (dolutegravir/rilpivirine) tablet KALETRA (lopinavir/ritonavir) solution, tablet Lamivudine/Zidovudine tablet Lopinavir/Ritonavir solution, tablet ODEFSEY (emtricitabine/rilpivirine/TAF) tablet		

PREZCOBIX (darunavir/cobicistat) tablet STRIBILD (elvitegravir/cobicistat/emtricitabine/TDF) tablet SYMFI/SYMFI LO (efavirenz/lamivudine/TDF) tablet SYMTUZA (darunavir/cobicistat/emtricitabine/TAF) tablet TEMIXYS (lamivudine/TDF) tablet TRIUMEQ (abacavir/dolutegravir/lamivudine) tablet TRIZIVIR (abacavir/lamivudine/zidovudine) tablet TRUVADA* (emtricitabine/TDF) tablet TAF – Tenofovir alafenamide TDF – Tenofovir disoproxil fumarate		

Therapeutic Drug Class: **TETRACYCLINES -** *Effective 7/1/2021*		
No PA Required	**PA Required**	Prior authorization for non-preferred tetracycline agents may be approved if member has trialed/failed a preferred doxycycline product AND preferred minocycline. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Prior authorization for liquid oral tetracycline formulations may be approved if member has difficulty swallowing and cannot take solid oral dosage forms. **Nuzyra** (omadacycline) prior authorization may be approved if member meets all of the following criteria: the above "non-preferred" prior authorization criteria and the following: • Member has trialed and failed† therapy with a preferred doxycycline product and preferred minocycline OR clinical rationale is provided describing why these medications cannot be trialed (including resistance and sensitivity) AND • Member has diagnosis of either Community Acquired Bacterial Pneumonia (CABP) or Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or clinical rationale and supporting literature describing/supporting intended use AND one of the following: o If member diagnosis is ABSSSI, member must have trial and failure† of sulfamethoxazole/trimethoprim product in addition to preferred tetracyclines OR o If member diagnosis is CABP, member must have trial and failure† of either a beta-lactam antibiotic (amoxicillin/clavulanic acid) or a macrolide (azithromycin)
Doxycycline hyclate capsules Doxycycline hyclate tablets Doxycycline monohydrate 50mg, 100mg capsule Doxycycline monohydrate tablets Minocycline capsules	Demeclocycline tablet DORYX (doxycycline DR) tablet Doxycycline hyclate DR tablet Doxycycline monohydrate 40mg, 75mg, 150mg capsule Doxycycline monohydrate suspension Minocycline IR, ER tablet MINOLIRA (minocycline) MORGIDOX (doxycycline/skin cleanser) NUZYRA (omadacycline)* SOLODYN ER (minocycline) Tetracycline capsule	

	VIBRAMYCIN (doxycycline) capsule, suspension, syrup XIMINO ER (minocycline)	AND • Maximum duration of use is 14 days †Failure is defined as lack of efficacy with 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction.)

III. Cardiovascular

Therapeutic Drug Class: **ALPHA-BLOCKERS** - *Effective 4/1/2021*

No PA Required	**PA Required**	
Prazosin capsule	MINIPRESS (prazosin) capsule	Non-preferred products may be approved following trial and failure of one preferred product (failure is defined as lack of efficacy with 4-week trial, allergy or intolerable side effects).

Therapeutic Drug Class: **BETA-BLOCKERS** - *Effective 4/1/2021*

Beta-Blockers, Single Agent

No PA Required	**PA Required**	
Acebutolol capsule Atenolol tablet Bisoprolol tablet BYSTOLIC[BNR] (nebivolol) tablet Carvedilol IR tablet Carvedilol ER capsule Labetalol tablet Metoprolol tartrate tablet Metoprolol succinate ER tablet Nadolol tablet Pindolol tablet Propranolol IR tablet, solution Propranolol ER capsule	Betaxolol tablet CORGARD (nadolol) tablet COREG (carvedilol) tablet COREG CR (carvedilol ER) capsule HEMANGEOL (propranolol) solution INDERAL LA/XL (propranolol ER) capsule INNOPRAN XL (propranolol ER) capsule KASPARGO (metoprolol succinate) sprinkle capsule LOPRESSOR (metoprolol tartrate) tablet Nebivolol tablet TENORMIN (atenolol) tablet Timolol tablet TOPROL XL (metoprolol succinate) tablet	Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). **HEMANGEOL (propranolol)** oral solution may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy. Maximum dose: 1.7 mg/kg twice daily **KAPSPARGO SPRINKLE (metoprolol succinate)** extended-release capsule may be approved for members ≥ 6 years of age that have difficulty swallowing or require medication administration via a feeding tube. Maximum dose: 200mg/day (adult); 50mg/day (pediatric) Grandfathering: Members currently stabilized on timolol oral tablet non-preferred products may receive approval to continue on that product.

Table 1: Receptor Selectivity and Other Properties of Preferred Beta Blockers

	ß$_1$	ß$_2$	Alpha-1 receptor antagonist	Intrinsic sympathomimetic activity (ISA)
Acebutolol	X			X
Atenolol	X			
Betaxolol	X			
Bisoprolol	X			
Carvedilol	X	X	X	
Labetalol	X	X	X	
Metoprolol succinate	X			

		Metoprolol tartrate	X			
		Nadolol	X	X		
		Nebivolol	X			
		Pindolol	X	X		X
		Propranolol	X	X		

Beta-Blockers, Anti-Arrhythmics		
No PA Required	**PA Required**	
Sotalol tablet	BETAPACE (sotalol) tablet SOTYLIZE (sotalol) solution	**SOTYLIZE (sotalol)** oral solution may be approved for members 3 days to < 5 years of age. For members ≥ 5 years of age, SOTYLIZE (sotalol) oral solution may be approved for members who-cannot swallow a sotalol tablet OR members that have trialed and failed therapy with one preferred product. (Failure is defined as allergy or intolerable side effects.) Maximum dose: 320 mg/day

Beta-Blockers, Combinations		
No PA Required	**PA Required**	
Atenolol/Chlorthalidone tablet Bisoprolol HCTZ tablet Metoprolol HCTZ tablet	Nadolol/Bendroflumethiazide tablet Propranolol HCTZ tablet TENORETIC (atenolol/chlorthalidone) tablet ZIAC (bisoprolol HCTZ) tablet	Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Therapeutic Drug Class: **CALCIUM CHANNEL-BLOCKERS -** *Effective 4/1/2021*		
Dihydropyridines (DHPs)		
No PA Required	**PA Required**	
Amlodipine tablet Felodipine ER tablet Nifedipine IR capsule Nifedipine ER tablet	ADALAT CC (nifedipine ER) tablet KATERZIA (amlodipine) suspension Isradipine capsule Nicardipine capsule Nimodipine capsule Nisoldipine ER tablet NORVASC (amlodipine) tablet NYMALIZE (nimodipine) solution, oral syringe	Non-preferred products may be approved following trial and failure of two preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. **NYMALIZE (nimodipine)** oral syringe may be approved for adult members (≥ 18 years of age) with subarachnoid hemorrhage who also have a feeding tube or have difficulty swallowing solid dosage forms. Maximum dose: 360 mg/day for 21 days (6 syringes/day or 126 syringes/21 days) **KATERZIA (amlodipine)** suspension may be approved if meeting the following: • The member has a feeding tube or confirmed difficulty swallowing solid oral dosage forms AND • For members < 6 years of age, the prescriber confirms that the member has already been receiving the medication following initiation in a hospital or other clinical setting

	PROCARDIA (nifedipine) capsule PROCARDIA (nifedipine ER) tablet SULAR (nisoldipine ER) tablet	
Non-Dihydropyridines (Non-DHPs)		
No PA Required Diltiazem IR tablet Diltiazem ER capsule Verapamil IR, ER tablet Verapamil ER 120 mg, 180 mg, 240 mg capsule	**PA Required** CALAN SR (verapamil ER) tablet CARDIZEM (diltiazem) tablet CARDIZEM CD/LA (diltiazem CD/ER) capsule, tablet TIAZAC ER (diltiazem ER) capsule Verapamil ER 360 mg capsule Verapamil PM ER 100 mg, 200 mg, 300 mg capsule VERELAN/PM (verapamil ER) capsule	Non-preferred products may be approved following trial and failure of three preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.
Therapeutic Drug Class: **ANGIOTENSIN MODIFIERS** - *Effective 7/1/2021*		
Angiotensin-converting enzyme inhibitors (ACE Inh)		
No PA Required Benazepril tablet Enalapril tablet Fosinopril tablet Lisinopril tablet Quinapril tablet Ramipril tablet	**PA Required** ACCUPRIL (quinapril) tablet ALTACE (ramipril) capsule Captopril EPANED powder/solution* (enalapril) LOTENSIN (benazepril) tablet Moexipril tablet Perindopril tablet PRINIVIL (lisinopril) tablet QBRELIS (lisinopril) solution*	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction). ***Epaned** (enalapril) solution may be approved without trial and failure of three preferred agents for members under the age of 5 years who cannot swallow a whole or crushed tablet. ***Qbrelis** (lisinopril) solution may be approved for members 6 years of age or older who cannot swallow a whole or crushed tablet and have trialed and failed Epaned (enalapril) solution. Failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

	Trandolapril tablet VASOTEC (enalapril) tablet ZESTRIL (lisinopril) tablet	
ACE Inhibitor Combinations		
No PA Required Amlodipine/Benazepril Enalapril HCTZ Lisinopril HCTZ	**PA Required** ACCURETIC (quinapril HCTZ) Benazepril HCTZ Captopril HCTZ Fosinopril HCTZ LOTENSIN HCT (benazepril HCTZ) LOTREL (amlodipine/benazepril) Quinapril HCTZ Trandolapril/Verapamil VASERETIC (enalapril HCTZ) ZESTORETIC (lisinopril HCTZ)	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).
Angiotensin II receptor blockers (ARBs)		
No PA Required Irbesartan Losartan Olmesartan Telmisartan Valsartan	**PA Required** ATACAND (candesartan) AVAPRO (irbesartan) BENICAR (olmesartan) Candesartan COZAAR (losartan) DIOVAN (valsartan) EDARBI (azilsartan) Eprosartan	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

	MICARDIS (telmisartan)	
ARB Combinations		
No PA Required (unless indicated*) Amlodipine/olmesartan Amlodipine/valsartan Irbesartan HCTZ Losartan HCTZ Olmesartan HCTZ Valsartan HCTZ ENTRESTO (sacubitril/valsartan)*	**PA Required** Amlodipine/valsartan/HCTZ ATACAND HCT (candesartan HCTZ) AVALIDE (irbesartan HCTZ) AZOR (amlodipine/olmesartan) BENICAR HCT (olmesartan HCTZ) Candesartan HCTZ DIOVAN HCT (valsartan HCTZ) EDARBYCLOR (azilsartan/chlorthalidone) EXFORGE (amlodipine/valsartan) EXFORGE HCT (amlodipine/valsartan/ HCTZ) HYZAAR (losartan HCTZ) MICARDIS HCT (telmisartan HCTZ) Olmesartan/amlodipine/HCTZ Telmisartan/amlodipine Telmisartan HCTZ TRIBENZOR (amlodipine/olmesartan/ HCTZ)	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction). ***ENTRESTO** (sacubitril/valsartan) may be approved for members if the following criteria are met: • Member is ≥ 1 year of age and has a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction (LVSD) and/or has chronic heart failure with a below-normal left ventricular ejection fraction (LVEF) • Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis codes related to the indicated use of the medication.
Renin Inhibitors & Renin Inhibitor Combinations		
	PA Required Aliskiren TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren HCTZ)	Non-preferred renin inhibitors and renin inhibitor combination products may be approved for members who have failed treatment with three preferred products from the angiotensin modifier class (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

		Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.
Therapeutic Drug Class: **PULMONARY ARTERIAL HYPERTENSION THERAPIES -** *Effective 1/1/2022*		
Phosphodiesterase Inhibitors		
***Must meet eligibility criteria** *REVATIO[BNR] (sildenafil) oral suspension *Sildenafil **(**generic Revatio) 20 mg tablet *Tadalafil 20mg tablet	**PA Required** ADCIRCA (tadalafil) tablet ALYQ (tadalafil) 20mg tablet REVATIO (sildenafil) 20mg tablet Sildenafil (generic Revatio) oral suspension	***Eligibility criteria for preferred products:** Preferred sildenafil and tadalafil tablet formulations may be approved for a diagnosis of pulmonary hypertension or right-sided heart failure. **REVATIO (sildenafil) suspension** may be approved for a diagnosis of pulmonary hypertension for members < 5 years of age or members ≥ 5 years of age who are unable to take/swallow tablets. Non-preferred products may be approved if meeting the following: • Member has a diagnosis of pulmonary hypertension **AND** • Member has trialed and failed treatment with preferred sildenafil tablet **AND** preferred tadalafil tablet. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction. Members who have been previously stabilized on a non-preferred product may receive approval to continue on the medication.
Endothelin Antagonists		
***Must meet eligibility criteria** *Ambrisentan tablet *TRACLEER [BNR] 62.5mg, 125mg (bosentan) tablet	**PA Required** Bosentan (generic Tracleer) 62.5mg, 125mg tablet LETAIRIS (ambrisentan) tablet OPSUMIT (macitentan) tablet TRACLEER (bosentan) 32mg tablet for suspension	***Eligibility Criteria for all agents in the class** Approval may be granted for a diagnosis of pulmonary hypertension. Member and prescriber should be enrolled in applicable REMS program for prescribed medication. Non-preferred agents may be approved for members who have trialed and failed two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Members who have been previously stabilized on a non-preferred product may receive approval to continue on the medication.
Prostanoids		
***Must meet eligibility criteria** *Epoprostenol (generic Flolan) vial *FLOLAN (epoprostenol) vial *ORENITRAM (treprostinil) ER tablet	**PA Required** REMODULIN (treprostinil) vial Treprostinil (generic Remodulin) vial TYVASO (treprostinil) inhalation solution	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. Non-preferred products may be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction).

*VENTAVIS (iloprost) inhalation solution	UPTRAVI (selexipag) tablet, dose pack, vial VELETRI (epoprostenol) vial	Members who have been previously stabilized on a non-preferred product may receive approval to continue on the medication.

Guanylate Cyclase (sGC) Stimulator		
	PA Required ADEMPAS (riociguat) tablet	**ADEMPAS (riociguat)** may be approved for members who meet the following criteria: • For members of childbearing potential: o Member is not pregnant and is able to receive monthly pregnancy tests while taking ADEMPAS and one month after stopping therapy **AND** o Member and their partners are utilizing one of the following contraceptive methods during treatment and for one month after stopping treatment (IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method) **AND** • Member has a CrCl ≥ 15 mL/min) and is not on dialysis **AND** • Member does not have severe liver impairment (Child Pugh C) **AND** • Prescriber attests to compliance with the ADEMPAS REMS Program **AND** • Member has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR** • Member has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Therapeutic Drug Class: **LIPOTROPICS** - *Effective 4/1/2021*		
Bile Acid Sequestrants		
No PA Required	**PA Required**	Non-preferred bile acid sequestrants may be approved if the member has failed treatment with 2 preferred products in the last 12 months (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Colesevelam tablet	Colesevelam packet	
Colestipol tablet	COLESTID (colestipol) tablet, granules	
Cholestyramine packet, light packet	Colestipol granules	
	QUESTRAN (cholestyramine/sugar) packet, powder	
	QUESTRAN LIGHT (cholestyramine/ aspartame) packet, powder	
	WELCHOL (colesevelam) tablet, packet	
Fibrates		
No PA Required	**PA Required**	

Fenofibrate capsule, tablet (generic Lofibra/Tricor) Gemfibrozil tablet	ANTARA (fenofibrate) capsule Fenofibric acid DR capsule Fenofibric acid tablet FENOGLIDE (fenofibrate) tablet LIPOFEN (fenofibrate) capsule LOPID (gemfibrozil) tablet TRICOR (fenofibrate nano) tablet TRILIPIX (fenofibric acid) capsule	Non-preferred fibrates may be approved if the member has failed treatment with generic gemfibrozil or generic fenofibrate and niacin ER in the last 12 months (failure is defined as lack of efficacy with 4-week trial of each drug, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Other Lipotropics		
No PA Required Ezetimibe tablet Niacin ER tablet *Omega-3 ethyl esters capsule (generic Lovaza)	**PA Required** Icosapent ethyl capsule LOVAZA (omega-3 ethyl esters) capsule NEXLETOL (bempedoic acid) tablet NEXLIZET (bempedoic acid/ezetimibe) tablet NIASPAN ER (niacin ER) tablet VASCEPA (icosapent ethyl) capsule ZETIA (ezetimibe) tablet	Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). *__Omega-3 ethyl esters__ (generic Lovaza) may be approved for members who have a baseline triglyceride level ≥ 500 mg/dL **Lovaza** (brand name) may be approved if meeting the following: • Member has a baseline triglyceride level ≥ 500 mg/dl AND • Member has failed an adequate trial of omega-3 Ethyl Esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) **Vascepa** (icosapent ethyl) may be approved if meeting the following: • Member has a baseline triglyceride level > 500 mg/dl AND • Member has failed an adequate trial of generic omega-3 ethyl esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) OR • Vascepa (icosapent ethyl) is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels ≥ 150mg/dL and LDL-C levels between 41-100 mg/dL AND member meets one of the following:

		○ Member is ≥ 45 years of age and has established atherosclerotic CV disease (e.g., coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) OR ○ Member is ≥ 50 years of age with diabetes mellitus and has <u>one or more</u> of the following additional risk factors for CV disease: ▪ Male ≥ 55 years of age or female ≥ 65 years of age ▪ Cigarette smoker ▪ Hypertension ▪ HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women ▪ hsCRP >3.00 mg/L (0.3 mg/dL) ▪ CrCl 30 to 59 mL/min ▪ Retinopathy ▪ Micro- or macroalbuminuria ▪ ABI <0.9 without symptoms of intermittent claudication Maximum Dose: Vascepa (icosapent ethyl) 4g daily
Therapeutic Drug Class: **STATINS** -*Effective 4/1/2021*		
No PA Required Atorvastatin tablet Lovastatin tablet Pravastatin tablet Rosuvastatin tablet Simvastatin tablet	**PA Required** ALTOPREV (lovastatin ER) tablet CRESTOR (rosuvastatin) tablet EZALLOR (rosuvastatin) sprinkle capsule Fluvastatin capsule, ER tablet LESCOL XL (fluvastatin ER) tablet LIPITOR (atorvastatin) tablet LIVALO (pitavastatin) tablet PRAVACHOL (pravastatin) tablet ZOCOR (simvastatin) tablet ZYPITAMAG (pitavastatin) tablet	Non-preferred Statins may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Age Limitations: Altoprev will not be approved for members < 18 years of age. Fluvastatin and lovastatin will not be approved for members < 10 years of age. Livalo will not be approved for members < 8 years of age.
Therapeutic Drug Class: **STATIN COMBINATIONS** -*Effective 4/1/2021*		
	PA Required Amlodipine /atorvastatin tablet CADUET (amlodipine/atorvastatin) tablet Ezetimibe/simvastatin tablet	Non-preferred Statin combinations may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Children:

	VYTORIN (ezetimibe/simvastatin) tablet	• Vytorin (ezetimibe/simvastatin) will not be approved for members < 18 years of age. • Caduet (amlodipine/atorvastatin) will not be approved for members < 10 years of age.

IV. Central Nervous System

Therapeutic Drug Class: **ANTICONVULSANTS -Oral-***Effective 10/1/2021*

No PA Required	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.***	Members currently stabilized (in outpatient or acute care settings) on any non-preferred medication in this class may receive prior authorization approval to continue on that medication. Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription. <u>Non-Preferred Products Newly Started for Treating Seizure Disorder or Convulsions:</u> ● Non-preferred medications newly started for members with a diagnosis of seizure disorder/convulsions may be approved if meeting the following criteria: o The medication is being prescribed by a neurologist **OR** o The medication is in consultation with a neurologist and meets the following: ▪ The prescription meets minimum age and maximum dose limits listed in Table 1 **AND** ▪ For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another anticonvulsant medication **AND** o The prescription meets additional criteria listed for any of the following: **APTIOM (eslicarbazepine):** o Member has history of trial and failure‡ of any carbamazepine-containing product **BRIVIACT (brivaracetam):** o Member is ≥1 month of age **AND** o Member has history of trial and failure‡ of any levetiracetam-containing product **DIACOMIT (stiripentol):** o Member is concomitantly taking clobazam **AND** o Member has diagnosis of seizures associated with Dravet syndrome **ELEPSIA XR (levetiracetam ER) tablet**
Barbiturates		
Phenobarbital elixir, soln, tab Primidone tablet	MYSOLINE (primidone)	
Hydantoins		
DILANTIN (phenytoin) 30 mg capsules DILANTIN suspension PHENYTEK (phenytoin ER) Phenytoin suspension, chewable, ER capsule	DILANTIN (phenytoin ER) infatab, 100 mg capsules PEGANONE (ethotoin) tablet	
Succinamides		
Ethosuximide capsule, solution	CELONTIN (methsuximide) capsule ZARONTIN (ethosuximide) capsule, solution	
Benzodiazepines		
Clobazam tablet Clonazepam tablet, ODT	Clobazam suspension KLONOPIN (clonazepam) tablet ONFI (clobazam) suspension, tablet	

	SYMPAZAN (clobazam)
Valproic Acid and Derivatives	
DEPAKOTE (divalproex DR) sprinkle capsule, tablet Divalproex capsule, DR tablet, ER tablet Valproic acid capsule, solution	DEPAKOTE ER (divalproex ER) tablet
Carbamazepine Derivatives	
Brand/generic changes effective 11/11/21 Carbamazepine IR tablet, ER tablet, chewable, ER capsule, suspension CARBATROL ER (carbamazepine) capsule Oxcarbazepine tablet, suspension TEGRETOL (carbamazepine) suspension TEGRETOL (carbamazepine) tablet TEGRETOL XR (carbamazepine ER) tablet TRILEPTAL (oxcarbazepine) suspension	APTIOM (eslicarbazepine) tablet EPITOL (carbamazepine) tablet EQUETRO (carbamazepine) capsule OXTELLAR XR (oxcarbazepine) tablet TEGRETOL (carbamazepine) capsule, chewable TRILEPTAL (oxcarbazepine) tablet
Lamotrigines	
LAMICTAL (lamotrigine) chewable/dispertab	LAMICTAL (lamotrigine) titration kit, tablet, ODT

- Member has history of trial and failure‡ of levetiracetam ER (KEPPRA XR)

EPIDIOLEX (cannabidiol):
- Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet Syndrome **OR**
- Member is ≥ 1 year of age and has a diagnosis of seizures associated with tuberous sclerosis complex (TSC).

FINTEPLA (fenfluramine):
- Member is ≥ 2 years of age AND has a diagnosis of seizures associated with Dravet syndrome

ONFI (clobazam) oral suspension:
- Member is ≥2 years of age **AND**
- Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) **AND**
- Member has documented swallowing difficulty due to young age and/or a medical condition, and is unable to use preferred tablet and capsule formulations **AND**
- Member is not taking a concomitant opioid (or concomitant opioid therapy has been determined to be clinically appropriate due to inadequacy of alternative treatment options)

OXTELLAR XR (oxcarbazepine ER):
- Member is ≥ 6 years of age **AND**
- Member is being treated for partial-onset seizures **AND**
- Member has history of trial and failure‡ of any carbamazepine or oxcarbazepine-containing product

SPRITAM (levetiracetam) tablet for suspension
- Member has history of trial and failure‡ of levetiracetam solution

SYMPAZAN (clobazam) film:
- Member has history of trial and failure‡ of clobazam tablet or solution **OR**
- Provider attests that member cannot take clobazam tablet or solution

<u>Non-Preferred Products Newly Started for Non-Seizure Disorder Diagnoses:</u>
- Non-preferred medications newly started for non-seizure disorder diagnoses may be approved if meeting the following criteria:
  - Member has history of trial and failure‡ of two preferred agents AND
  - The prescription meets minimum age and maximum dose limits listed in Table 1.

‡Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or documented contraindication to therapy, or inability to take

Lamotrigine tablet, chewable/disperse tabs	LAMICTAL XR (lamotrigine ER) tablet, titration kit Lamotrigine ODT, ER tablet, IR/ODT titration kit
Topiramates	
TOPAMAX (topiramate) sprinkle capsule Topiramate tablet, sprinkle capsule	QUDEXY XR (topiramate) capsule TOPAMAX (topiramate) tablet Topiramate ER capsule TROKENDI XR (topiramate ER) capsule
Brivaracetam/Levetiracetam	
Levetiracetam IR tablet, ER tablet, solution	BRIVIACT (brivaracetam) solution, tablet ELEPSIA XR (levetiracetam ER) tablet KEPPRA (levetiracetam) tablet, solution KEPRA XR (levetiracetam ER) tablet SPRITAM (levetiracetam) tablet
Other	
FELBATOL[BNR] (felbamate) tablet, suspension Zonisamide capsule	BANZEL (rufinamide) suspension, tablet DIACOMIT (stiripentol) capsule, powder packet EPIDIOLEX (cannabidiol) solution Felbamate tablet, suspension FINTEPLA (fenfluramine) solution FYCOMPA (perampanel) suspension, tablet GABITRIL (tiagabine) tablet

preferred formulation. Members identified as HLA-B*15:02 positive, carbamazepine and oxcarbazepine should be avoided per Clinical Pharmacogenetics Implementation Consortium Guideline. This may be considered a trial for prior authorization approvals of a non-preferred agent.

Table 1: Non-preferred Product Minimum Age and Maximum Dose

	Minimum Age**	Maximum Dose**
Barbiturates		
primidone (MYSOLINE)		2,000 mg per day
Benzodiazepines		
clobazam (ONFI)	2 years	40 mg per day
clobazam film (SYMPAZAN)	2 years	40 mg per day
clobazam suspension	2 years	40 mg per day
clonazepam (KLONOPIN)		20 mg per day
Brivaracetam/Levetiracetam		
brivaracetam (BRIVIACT)	1 month	200 mg per day
levetiracetam (KEPPRA)	1 month	3,000 mg per day
levetiracetam (SPRITAM)	4 years	3,000 mg per day
levetiracetam ER (ELEPSIA XR)	12 years	3,000 mg per day
levetiracetam ER (KEPPRA XR)	12 years	3,000 mg per day
Carbamazepine Derivatives		
carbamazepine (EPITOL)		1,600 mg per day
carbamazepine ER (EQUETRO)		1,600 mg per day
eslicarbazepine (APTIOM)	4 years	1,600 mg per day
oxcarbazepine ER (OXTELLAR XR)	6 years	2,400 mg per day
Hydantoins		
ethotoin (PEGANONE)		3,000 mg per day
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine (LAMICTAL ODT)	2 years	500 mg per day
lamotrigine ER (LAMICTAL XR)	13 years	600 mg per day
Succinamides		
ethosuximide (ZARONTIN)		20 mg/kg/day
methsuximide (CELONTIN)		Not listed
Valproic Acid and Derivatives		
divalproex ER (DEPAKOTE ER)	10 years	60 mg/kg/day
Topiramates		
topiramate (TOPAMAX)	2 years	400 mg per day
topiramate ER (QUDEXY XR)	2 years	400 mg per day
topiramate ER (TROKENDI XR)	6 years	400 mg per day

	Rufinamide suspension, tablet SABRIL (vigabatrin) powder packet, tablet Tiagabine tablet Vigabatrin tablet, powder packet VIMPAT (lacosamide) solution, kit, tablet XCOPRI (cenobamate) tablet, pack	**Other** | | | cannabidiol (EPIDIOLEX) | 1 year | 20 mg/kg/day cenobamate (XCOPRI) | 18 years | 400 mg per day felbamate tablet, suspension | 2 years | fenfluramine (FINTEPLA) | 2 years | 26 mg per day lacosamide (VIMPAT) | 1 month | 400 mg per day perampanel (FYCOMPA) | 4 years | 12 mg per day rufinamide (BANZEL) tablet and suspension | 1 year | 3,200 mg per day stiripentol (DIACOMIT) | 2 years | 3,000 mg per day tiagabine | 12 years | 64 mg per day tiagabine (GABITRIL) | 12 years | 64 mg per day vigabatrin | 1 month | 3,000 mg per day vigabatrin (SABRIL) | 1 month | 3,000 mg per day vigabatrin (VIGADRONE) powder packet | 1 month | 3,000 mg per day zonisamide (ZONEGRAN) | 16 years | 600 mg per day **Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis.

Therapeutic Drug Class: **NEWER GENERATION ANTI-DEPRESSANTS** -*Effective 1/1/2022*		
No PA Required Bupropion IR, SR, XL tablet Citalopram tablet, solution Desvenlafaxine succinate ER tablet Duloxetine (generic Cymbalta) capsule Escitalopram tablet Fluoxetine capsules, solution Fluvoxamine tablet Mirtazapine tablet, ODT Paroxetine IR tablet Sertraline tablet, solution Trazodone tablet	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** APLENZIN (bupropion ER) tablet Bupropion XL (generic Forfivo XL) tablet CELEXA (citalopram) tablet CYMBALTA (duloxetine) capsule Desvenlafaxine fumarate ER tablet DRIZALMA (duloxetine) sprinkle capsule Duloxetine (generic Irenka) capsule EFFEXOR XR (venlafaxine ER) capsule Escitalopram solution FETZIMA (levomilnacipran ER) capsule	Prior authorization for Fetzima, Trintellix, or Viibryd may be approved for members who have failed an adequate trial with four preferred newer generation anti-depressant products (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction). All non-preferred products not listed above may be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction). **Citalopram** doses higher than 40mg/day for ≤60 years of age and 20mg/day for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information. Members currently stabilized on a Non-preferred newer generation antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

Venlafaxine IR tablet Venlafaxine ER capsules	Fluoxetine IR tablet, fluoxetine DR capsule Fluvoxamine ER capsule FORFIVO XL (bupropion ER) tablet LEXAPRO (escitalopram) tablet Nefazodone tablet Paroxetine ER tablet PAXIL (paroxetine) tablet, suspension PAXIL CR (paroxetine ER) tablet PEXEVA (paroxetine mesylate) tablet PRISTIQ (desvenlafaxine succinate ER) tablet PROZAC (fluoxetine) Pulvule REMERON (mirtazapine) tablet, Soltab (ODT) TRINTELLIX (vortioxetine) tablet Venlafaxine ER tablets VIIBRYD (vilazodone) tablet WELLBUTRIN SR, XL (bupropion) tablet ZOLOFT (sertraline) tablet, solution	
Therapeutic Drug Class: **MONOAMINE OXIDASE INHIBITORS (MAOIs)** -*Effective 1/1/2022*		
	PA Required EMSAM (selegiline) patch MARPLAN (isocarboxazid) tablet NARDIL (phenelzine) tablet Phenelzine tablet	Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred anti-depressant products. If three preferred anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred anti-depressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

	Tranylcypromine tablet	Members currently stabilized on a Non-preferred MAOi antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**
Therapeutic Drug Class: **TRICYCLIC ANTI-DEPRESSANTS (TCAs)** -*Effective 1/1/2022*		
No PA Required Amitriptyline tablet Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule Doxepin solution Imipramine HCl tablet Nortriptyline capsule, solution	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** Amoxapine tablet ANAFRANIL (clomipramine) capsule Clomipramine capsule Desipramine tablet Imipramine pamoate capsule Maprotiline tablet NORPRAMIN (desipramine) tablet PAMELOR (nortriptyline) capsule Protriptyline tablet Trimipramine capsule	Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction) Members currently stabilized on a Non-preferred TCA antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.** Silenor (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P
Therapeutic Drug Class: **ANTI-PARKINSON'S AGENTS** -*Effective 4/1/2021*		
Dopa decarboxylase inhibitors, dopamine precursors and combinations		
No PA Required Carbidopa/Levodopa IR, ER tablet Carbidopa/Levodopa/Entacapone tablet	**PA Required** Carbidopa tablet Carbidopa/Levodopa ODT DUOPA (carbidopa/levodopa) suspension INBRIJA (levodopa) capsule for inhalation LODOSYN (carbidopa) tablet RYTARY ER (carbidopa/levodopa) capsule	Non-preferred agents may be approved with adequate trial and failure of carbidopa-levodopa IR and ER formulations (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Carbidopa or levodopa single agent products may be approved for members with diagnosis of Parkinson's Disease as add-on therapy to carbidopa-levodopa. Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria.

	SINEMET (carbidopa/levodopa) IR tablet STALEVO (carbidopa/levodopa/ entacapone) tablet	Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
MAO-B inhibitors		
No PA Required Selegiline capsule Selegiline tablet	**PA Required** AZILECT (Rasagiline) tablet Rasagiline tablet XADAGO (safinamide) tablet ZELAPAR (selegiline) ODT	Non-preferred agents may be approved with adequate trial and failure of selegiline capsule or tablet (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred medications that are not prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Dopamine Agonists		
No PA Required Pramipexole IR tablet Ropinirole IR tablet	**PA Required** APOKYN (apomorphine) SC cartridge Bromocriptine capsule, tablet CYCLOSET (bromocriptine) tablet KYNMOBI (apomorphine) SL film MIRAPEX (pramipexole) ER tablet NEUPRO (rotigotine) patch PARLODEL (bromocriptine) Pramipexole ER tablet REQUIP (ropinirole) XR tablet	Non-preferred agents may be approved with adequate trial and failure of ropinirole IR AND pramipexole IR (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). **APOKYN (apomorphine subcutaneous cartridge)** may be approved if meeting the following: • APOKYN (apomorphine) is being used as an adjunct to other medications for acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease AND • Due to the risk of profound hypotension and loss of consciousness, member is not concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron. Maximum dose: 6mg (0.6mL) three times per day **KYNMOBI (apomorphine sublingual film)** may be approved if meeting the following: • KYNMOBI (apomorphine) is being used for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease AND

	Ropinirole ER tablet	• Due to the risk of profound hypotension and loss of consciousness, member must not be concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron. Maximum dose: 30mg five times per day Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Other Parkinson's agents		
No PA Required Amantadine capsule, tablet, solution/syrup Benztropine tablet Trihexyphenidyl tablet, elixir	**PA Required** COMTAN (entacapone) tablet Entacapone tablet GOCOVRI ER (amantadine ER) capsule NOURIANZ (istradefylline) tablet ONGENTYS (opicapone) capsule OSMOLEX ER (amantadine) tablet TASMAR (tolcapone) tablet Tolcapone tablet	Non-preferred agents may be approved with adequate trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Therapeutic Drug Class: **BENZODIAZEPINES (NON-SEDATIVE HYPNOTIC)** *Effective 4/1/2021*		
No PA Required (*may be subject to age limitations) Alprazolam IR, ER tablet* Chlordiazepoxide capsule* Clorazepate tablet*	**PA Required** Alprazolam Intensol ATIVAN (lorazepam) tablet Diazepam Intensol	Non-preferred products may be approved following trial and failure of three preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. <u>Children</u>: Prior authorization will be required for all agents when prescribed for children <18 years of age (with the exception of oral solution products) and may be approved with prescriber verification of necessity of use for member age.

<table>
<tr>
<td>Diazepam tablet*, solution

Lorazepam tablet*, solution

Oxazepam capsule*</td>
<td>TRANXENE T-TAB (clorazepate) tablet

XANAX (alprazolam) tablet, ODT

XANAX XR (alprazolam ER) tablet</td>
<td>
Diazepam Intensol may be approved following trial and failure of the preferred 5 mg/5 mL oral solution. Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy.

All benzodiazepine anxiolytics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy.

Grandfathering:

Members < 65 years of age who are currently stabilized on a non-preferred benzodiazepine medication may receive approval to continue that medication.
Members < 18 years of age who are currently stabilized on a non-preferred oral solution product may receive authorization to continue that medication.

Prior authorization will be required for prescribed doses that exceed the maximum (Table 1).
<table>
<tr><th colspan="3">Table 1 Maximum Doses</th></tr>
<tr><th>Product</th><th>Maximum Daily Dose</th><th>Maximum Monthly Dose</th></tr>
<tr><td>Alprazolam tablet
Alprazolam ER tablet
Alprazolam ODT
XANAX (alprazolam) tablet
XANAX XR (alprazolam ER) tablet
Alprazolam Intensol oral concentrate 1 mg/mL</td><td>Adults ≥ 18 years:
10 mg/day</td><td>Total of 300 mg from all dosage forms per 30 days</td></tr>
<tr><td>Clorazepate tablet
TRANXENE (clorazepate) T-Tab</td><td>>12 years: 90 mg/day
Children 9-12 years: up to 60 mg/day</td><td>Total of 2,700 mg (adults) and 1,800 mg (children) from all tablet strengths per 30 days</td></tr>
<tr><td>Chlordiazepoxide capsule</td><td>Adults ≥ 18 years: 300 mg/day
Children 6-17 years: up to 40 mg/day (pre-operative apprehension and anxiety)</td><td>Total of 9,000 mg (adults) and 120 mg (children, pre-op therapy) from all tablet strengths per 30 days</td></tr>
<tr><td>Diazepam Intensol oral concentrate 5 mg/mL

Diazepam solution 5 mg/5 mL</td><td>Adults ≥ 18 years: 40 mg/day
Children: N/A</td><td>Total of 1200 mg from all dosage forms per 30 days</td></tr>
<tr><td>Diazepam tablet</td><td>Adults ≥ 18 years: 40 mg/day
Children 6 months to 18 years: up to 10 mg/day</td><td>Total of 1200 mg (adults) and 300 mg (pediatrics) from all dosage forms per 30 days</td></tr>
<tr><td>ATIVAN (lorazepam) Intensol concentrate 2 mg/mL
ATIVAN (lorazepam) tablet
Lorazepam oral concentrated soln 2 mg/mL</td><td>Adults ≥ 18 years: 10 mg/day
Children: N/A</td><td>Total of 300 mg from all dosage forms per 30 days</td></tr>
</table>
</td>
</tr>
</table>

		Lorazepam tablet		
		Oxazepam capsule	Adults ≥ 18 years: 120 mg/day Children 6-18 years: absolute dosage not established	Total of 3600 mg from all dosage forms per 30 days

Therapeutic Drug Class: **ANXIOLYTIC, NON- BENZODIAZEPINES** - *Effective 4/1/2021*		
No PA Required Buspirone tablet	**PA Required**	Non-preferred products may be approved following trial and failure of buspirone. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

Therapeutic Drug Class: **ATYPICAL ANTI-PSYCHOTICS - Oral and Topical**- *Effective 4/1/2021* **For injectable Atypical Antipsychotics please see Appendix P for criteria**		
No PA Required* Aripiprazole tablet Clozapine tablet LATUDA (lurasidone) **2nd line**** Olanzapine tablet, ODT Quetiapine IR tablet*** Quetiapine ER tablet Risperidone tablet, ODT, oral solution Ziprasidone	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** ABILIFY (aripiprazole) tablet, MyCite Aripiprazole oral solution****, ODT Asenapine SL tablet CAPLYTA (lumateperone) capsule Clozapine ODT CLOZARIL (clozapine) tablet, ODT FANAPT (iloperidone) tablet, pack FAZACLO (clozapine) ODT GEODON (ziprasidone) capsule INVEGA ER (paliperidone) tablet NUPLAZID (pimavanserin) capsule, tablet Olanzapine/Fluoxetine capsule Paliperidone ER tablet	Non-preferred products may be approved for members meeting all of the following: • Medication is being prescribed for an FDA-Approved indication AND • Prescription meets dose and age limitations (Table 1) AND • Member has history of trial and failure of three preferred products with FDA approval for use for the prescribed indication (failure defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing) *Age Limits: All products including preferred products will require a PA for members younger than the FDA approved age for the agent (Table 1). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. **Atypical Antipsychotic prescriptions for members under 5 years of age may require a provider-provider telephone consult with a child and adolescent psychiatrist (provided at no cost to provider or member).** ****Latuda (lurasidone)** may be approved for the treatment of schizophrenia or bipolar depression if the member has tried and failed treatment with one preferred product (qualifying diagnosis verified by AutoPA). *****Quetiapine IR** when given at sub-therapeutic doses may be restricted for therapy. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 1) stabilized on <150mg quetiapine IR per day. ******Aripiprazole solution**: Aripiprazole tablet quantity limit is 2 tablets/day for pediatric members to allow for incremental dose titration and use of the preferred tablet formulation should be considered for dose titrations when possible and clinically appropriate. If incremental dose cannot be achieved with titration of the aripiprazole

	REXULTI (brexpiprazole) tablet RISPERDAL (risperidone) tablet, oral solution SAPHRIS (asenapine) SL tablet SECUADO (asenapine) patch SEROQUEL IR (quetiapine IR)*** tablet SEROQUEL XR (quetiapine ER)*** tablet SYMBYAX (olanzapine/fluoxetine) capsule VERSACLOZ (clozapine) suspension VRAYLAR (cariprazine) capsule ZYPREXA (olanzapine) tablet ZYPREXA ZYDIS (olanzapine) ODT	tablet for members < 18 years of age OR for members unable to swallow solid tablet dosage form, aripiprazole solution may be approved. For all other cases, aripiprazole solution is subject to meeting non-preferred product approval criteria listed above. **Nuplazid (pimavanserin tartrate)** may be approved for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis AND following trial and failure of therapy with quetiapine or clozapine (failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy). **Abilify MyCite** may be approved if meeting all of the following: • Member has history of adequate trial and failure of 5 preferred agents (one trial must include aripiprazole tablet). Failure is defined as lack of efficacy with 6-week trial on maximally tolerated dose, allergy, intolerable side effects, significant drug-drug interactions AND • Information is provided regarding adherence measures being recommended by provider and followed by member (such as medication organizer or digital medication reminders) AND • Member has history of adequate trial and failure of 3 long-acting injectable formulations of atypical antipsychotics, one of which must contain aripiprazole (failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, significant drug-drug interactions) AND • Abilify MyCite is being used with a MyCite patch and member is using a compatible mobile application. AND • Medication adherence information is being shared with their provider via a web portal or dashboard. Quantity Limits: Quantity limits will be applied to all products (Table 1). In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. Grandfathering: Members currently stabilized on a non-preferred atypical antipsychotic or Latuda can receive approval to continue therapy with that agent for one year.

Table 1 Atypical Antipsychotics – FDA Approved Indication, Age Range, Quantity and Maximum Dose

Brand	Generic	Approved Indications	Age Range	Maximum Daily Dose by Age/Indication	Quantity and Maximum Dose Limitations
ABILIFY	aripiprazole	Schizophrenia Bipolar I Disorder (adult) Bipolar I Disorder (peds) Irritability w/autistic disorder Tourette's disorder	≥ 13 years ≥ 18 years 10-17 years 6-17 years 6-18 years	30 mg 30 mg 15 mg 15 mg 20 mg	Maximum one tablet per day (maximum of two tablets per day allowable for members < 18 years of age to accommodate for incremental dose changes)
CLOZARIL	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg per day

CAPLYTA	lumateperone	Schizophrenia	≥ 18 years	42 mg	Maximum dosage of 42mg per day
FAZACLO	clozapine	Treatment-resistant Schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg per day
FANAPT	iloperidone	Schizophrenia	≥ 18 years	24 mg	Maximum two tablets per day
GEODON	ziprasidone	Schizophrenia Bipolar I Disorder	≥ 18 years ≥ 18 years	200 mg 160 mg	Maximum two capsules per day
INVEGA	paliperidone	Schizophrenia & schizoaffective disorder	≥ 12 years and weight ≥ 51 kg ≥ 12 years and weight < 51 kg	12 mg 6 mg	Maximum one capsule per day
LATUDA	lurasidone	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar I disorder (adult) Bipolar I disorder (peds)	≥ 18 years 13-17 years ≥ 18 years 10–17 years	160 mg 80 mg 120 mg 80 mg	Maximum one tablet per day (If dosing 160mg for schizophrenia, then max of two tablets per day)
NUPLAZID	pimavanserin	Parkinson's disease psychosis	≥ 18 years	34 mg	Maximum dosage of 34mg per day
RISPERDAL	risperidone	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar mania (adult & peds) Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5–17 years	12mg 6 mg 6 mg 3 mg	Maximum dosage of 12mg/day
REXULTI	brexpiprazole	Schizophrenia (adult) Adjunctive treatment of MDD	≥ 18 years	4 mg 3 mg	Maximum of 3mg/day for MDD adjunctive therapy, Maximum of 4mg/day for schizophrenia
SAPHRIS	asenapine	Schizophrenia (adult) Bipolar mania or mixed episodes	≥ 18 years ≥ 10 years	20 mg 20 mg	Maximum two tablets per day
SECUADO	asenapine patch	Schizophrenia (adult)	≥ 18 years	7.6 mg/ 24 hours	Maximum 1 patch per day
SEROQUEL	quetiapine	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar I mania or mixed (adult) Bipolar I mania or mixed (peds) Bipolar I depression (adults) Bipolar I Disorder Maintenance	≥ 18 years 13-17 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	750 mg 800 mg 800 mg 600 mg 300 mg 800 mg	Maximum three tablets per day
SEROQUEL XR	quetiapine ER	Schizophrenia (adult/adolescent) Bipolar I mania (adult) Bipolar I mania (peds) Bipolar I depression (adults) Adjunctive treatment of MDD	≥ 13 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	800 mg 800 mg 600 mg 300 mg 300 mg	Maximum one tablet per day (for 300mg & 400mg tablets max 2 tablets per day)
SYMBYAX	olanzapine/ fluoxetine	Acute depression in Bipolar I Disorder Treatment resistant depression (MDD)	≥ 10 years	12 mg olanzapine/ 50 mg fluoxetine	Maximum three capsules per day (18mg olanzapine/75mg fluoxetine)

VRAYLAR	cariprazine	Schizophrenia Acute manic or mixed episodes with Bipolar I Disorder Depressive episodes with Bipolar I disorder	≥ 18 years ≥ 18 years ≥ 18 years	6 mg 6 mg 3 mg	Maximum dosage of 6mg/day
ZYPREXA ZYPREXA ZYDIS	olanzapine	Schizophrenia Acute manic or mixed episodes with Bipolar I Disorder	≥ 13 years	20 mg	Maximum one tablet per day

Therapeutic Drug Class: **CALCITONIN GENE – RELATED PEPTIDE INHIBITORS (CGRPis)** -*Effective 4/1/2021*

PA Required for all agents

*AIMOVIG (erenumab-aooe) auto-injector

*EMGALITY 120mg (galcanezumab-gnlm) pen, syringe

AJOVY (fremanezumab-vfrm) syringe

EMGALITY 100mg (galcanezumab-gnlm) syringe

NURTEC (rimegepant) ODT

UBRELVY (ubrogepant) tablet

***Emgality 120mg** (galcanezumab) or **Aimovig** (erenumab) may be approved for members meeting Migraine Prevention Prior Authorization Criteria below.

Migraine Prevention Prior Authorization Criteria (must meet all of the following):

- Member is 18 years of age or older AND
- Member is in need of preventative therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura AND
- Member has tried and failed 2 oral preventative pharmacological agents listed as Level A per American Headache Society/American Academy of Neurology (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- Headache count: If prescribed for episodic migraine member has history of 4-14 migraine days per month OR if prescribed for chronic migraine member has history of 15 or more headache days per month where 8 or more were migraine days for three or more months AND
- Member does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months AND
- Prescription meets one of the following:
  - Medication is not prescribed for chronic migraine with medication overuse headache OR
  - Member is prescribed Aimovig for chronic migraine with medication overuse headache resulting from taking triptans ≥ 10 days/month, non-narcotic analgesics ≥ 15 days/month (such as acetaminophen, NSAID), or a combination of analgesics ≥ 10 days/month (including non-narcotic, ergot, opioid, butalbital)

AND

- Initial authorization will be limited to the following:
  - For episodic migraine: Initial authorization will be for 6 months. Continuation (12-month authorization) will require documentation of clinically significant improvement after 4 months use (and documentation of number of migraine days per month)
  - For chronic migraine: Initial authorization will be for 4 months. Continuation (12-month authorization) will require documentation of

		clinically significant improvement after 3 months use (and documentation of number of migraine days per month) <u>Non-Preferred Medications for Migraine Prevention</u>: Non-preferred medications for migraine prevention may be approved if the member meets the Migraine Prevention Prior Authorization Criteria above AND the member has history of adequate trial and failure of Emgality 120mg AND Aimovig therapy (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction). Members taking a non-preferred agent for migraine prevention that have not shown clinically significant improvement for 4 months for acute episodic migraine treatment or 3 months for chronic migraine treatment will be allowed to transition to a preferred CGRP agent without meeting the "headache count" criteria listed above. <u>Non-Preferred Medications for Acute Migraine Treatment or Cluster Headache Treatment:</u> Non-preferred medications for acute migraine treatment may be approved for members meeting all of the following: • Member is 18 years of age or older AND • Medication is being prescribed to treat migraine headache with moderate to severe pain AND • Member is not receiving an injectable form of CGRP medication for any indication AND • Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction): o Three triptans AND o Two NSAID agents Non-preferred medications for treatment of cluster headache may be approved for members meeting all of the following: • Member is 19-65 years of age AND • Member meets diagnostic criteria for episodic cluster headache (has had no more than 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the week prior to this medication being prescribed) AND • Member is not taking other preventative medications to reduce the frequency of cluster headache attacks AND • Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction): o Oxygen therapy AND o Sumatriptan subcutaneous or intranasal AND

		○ Zolmitriptan intranasal AND • Member is not prescribed this medication for medication overuse headache AND • Member does not have ECG abnormalities compatible with acute cardiovascular event or conduction delay AND • Member does not have a history within the last 6 months of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism AND • Member does not have a history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina, clinical evidence of peripheral vascular disease, or diagnosis of Raynaud's AND • Initial authorization will be limited to 8 weeks. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4-week period. <u>Maximum Dosing:</u> Aimovig (erenumab): 140mg per 30 days Emgality 120mg (galcanezumab): 240mg once as first loading dose then 120mg monthly Emgality 100mg (galcanezumab): 300mg per 30 days Ajovy (fremanezumab): 225mg monthly or 675mg every three months Ubrelvy 50mg (ubrogepant): 16 tablets/30 days (800mg per 30 days) Ubrelvy 100mg (ubrogepant): 16 tablets/30 days (1600mg per 30 days) Nurtec (rimegepant): 15 tablets/30 days (1125mg per 30 days)
Therapeutic Drug Class: **LITHIUM AGENTS** -*Effective 4/1/2021*		
No PA Required Lithium Carbonate capsule Lithium Carbonate tablet Lithium ER tablet	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** LithoBID ER (lithium ER) tablet Lithium Citrate soln	Non-preferred products may be approved with trial and failure of one preferred agent (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, intolerance to dosage form). Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Therapeutic Drug Class: **NEUROCOGNITIVE DISORDER AGENTS** -*Effective 4/1/2021*		
***Must meet eligibility criteria** *Donepezil 5mg, 10mg tablet *Donepezil ODT *Memantine IR tablets	**PA Required** ARICEPT (donepezil) tablet Donepezil 23mg tablet EXELON (rivastigmine) patch	***Eligibility criteria for Preferred Agents –** All preferred products may be approved without PA if the member has a diagnosis of neurocognitive disorder which can be verified by SMART PA. Non-preferred products may be approved if the member has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

*Rivastigmine capsule, patch	Galantamine IR tablet, solution Galantamine ER capsule Memantine ER capsule, IR solution MESTINON (pyridostigmine) tablet, syrup NAMENDA (memantine) tablet NAMENDA XR (memantine ER) capsule NAMZARIC (memantine/donepezil ER) capsule RAZADYNE ER (galantamine) capsule	Members currently stabilized on a non-preferred product may receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of neurocognitive disorder.

Therapeutic Drug Class: **SEDATIVE HYPNOTICS** -*Effective 4/1/2021*		
Non-Benzodiazepines		
No PA Required* (unless age, dose, or duplication criteria apply) Eszopiclone tablet Zaleplon capsule Zolpidem IR tablet Zolpidem ER tablet	**PA Required** AMBIEN (zolpidem) tablet AMBIEN CR (zolpidem ER) tablet BELSOMRA (suvorexant) tablet DAYVIGO (lemoborexant) tablet EDLUAR (zolpidem) SL tablet INTERMEZZO (zolpidem) SL tablet LUNESTA (eszopiclone) tablet Ramelteon tablet ROZEREM (ramelteon) tablet Zolpidem SL tablet	Non-preferred non-benzodiazepine sedative hypnotics may be approved for members who have failed treatment with two preferred non-benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). <u>Children:</u> Prior authorization will be required for all agents for children < 18 years of age. <u>Duplications:</u> Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved). All sedative hypnotics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy. **Belsomra** (suvorexant) may be approved for adult members that meet the following: • Members has trialed and failed therapy with two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND • Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND • Member does not have a diagnosis of narcolepsy **Dayvigo** (lemborexant) may be approved for adult member that meet the following: • Member has trialed and failed therapy with two preferred agents AND Belsomra (surovexant). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND

		• Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND • Member does not have a diagnosis of narcolepsy **Rozerem** (ramelteon) may be approved for adult members with a history/concern of substance abuse or for documented concern of diversion within the household without failed treatment on a preferred agent Prior authorization will be required for prescribed doses exceeding maximum (Table 1).
Benzodiazepines		
No PA Required* (unless age, dose, or duplication criteria apply) Temazepam 15mg, 30mg capsule Triazolam tablet	**PA Required** Estazolam tablet Flurazepam capsule HALCION (triazolam) tablet RESTORIL (temazepam) capsule Temazepam 7.5mg, 22.5mg capsule	Non-preferred benzodiazepine sedative hypnotics may be approved for members who have trialed and failed therapy with two preferred benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). **Temazepam 7.5mg and 22.5 mg** may be approved if the member has trialed and failed temazepam 15mg or 30mg AND one other preferred product (failure is defined as lack of efficacy with a 2-week trail, allergy, intolerable side effects, or significant drug-drug interaction). <u>Children:</u> Prior authorization will be required for all sedative hypnotic agents when prescribed for children < 18 years of age. <u>Duplications:</u> Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved). All sedative hypnotics will require prior authorization for member's ≥ 65 years of age when exceeding 90 days of therapy. <u>Grandfathering:</u> Members currently stabilized on a non-preferred benzodiazepine medication may receive authorization to continue that medication. Prior authorization will be required for prescribed doses exceeding maximum (Table 1).

Table 1: Sedative Hypnotic Maximum Dosing

Brand	Generic	Maximum Dose
Non-Benzodiazepine		
Ambien CR	Zolpidem CR	12.5 mg/day
Ambien IR	Zolpidem IR	10 mg/day
Belsomra	Suvorexant	20 mg/day

Dayvigo	Lemborexant	10mg/day
Edluar	Zolpidem sublingual	10 mg/day
Intermezzo	Zolpidem sublingual	Men: 3.5mg/day Women: 1.75 mg/day
Lunesta	Eszopiclone	3 mg/day
Sonata	Zaleplon	20 mg/day
Rozerem	Ramelteon	8 mg/day
Benzodiazepine		
Halcion	Triazolam	0.5 mg/day
Restoril	Temazepam	30 mg/day
-	Estazolam	2 mg/day
-	Flurazepam	30 mg/day
-	Quazepam	15 mg/day

Therapeutic Drug Class: **SKELETAL MUSCLE RELAXANTS** -*Effective 7/1/2021*

No PA Required (if under 65 years of age)*	**PA Required**	
Baclofen (generic Lioresal) Cyclobenzaprine (generic Flexeril) 5mg and 10mg tablet Methocarbamol Tizanidine tablet	AMRIX ER (cyclobenzaprine ER) Carisoprodol Carisoprodol/Aspirin Chlorzoxazone Cyclobenzaprine 7.5mg tabs Cyclobenzaprine ER capsule DANTRIUM (dantrolene) *Dantrolene FEXMID (cyclobenzaprine) LORZONE (chlorzoxazone) Metaxalone NORGESIC FORTE (orphenadrine/aspirin/caffeine) Orphenadrine ER	All agents in this class will require a PA for members 65 years of age and older. The maximum allowable approval will be for a 7-day supply. Non-preferred skeletal muscle relaxants may be approved for members who have trialed and failed‡ three preferred agents. Authorization for any **CARISOPRODOL** product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products within the last 6 months. ***Dantrolene** may be approved for members 5-17 years of age who have trialed and failed‡ one preferred agent and meet the following criteria: ● Documentation of age-appropriate liver function tests AND ● One of following diagnoses: Multiple Sclerosis, Cerebral Palsy, stroke, upper motor neuron disorder, or spinal cord injury ● Dantrolene will be approved for the period of one year ● If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age ‡Failure is defined as: lack of efficacy with 14 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.

	ROBAXIN (methocarbamol) SKELAXIN (metaxalone) SOMA (carisoprodol) Tizanidine capsules ZANAFLEX (tizanidine)	
Therapeutic Drug Class: **STIMULANTS AND RELATED AGENTS** -*Effective 10/1/2021*		
***No PA Required (if age, max daily dose, and diagnosis met)** *Brand/generic changes effective 2/23/22* ADDERALL XR[BNR] (mixed amphetamine salts ER) Amphetamine salts, mixed (generic Adderall) tablet Armodafinil tablet Atomoxetine capsule CONCERTA[BNR] (methylphenidate ER) tablet Dexmethylphenidate IR tablet Dexmethylphenidate ER capsule Guanfacine ER tablet Methylphenidate (generic Ritalin) tablet Methylphenidate 36mg ER tablet (generic Concerta) - *Patriot Only*- Modafinil tablet	**PA Required** ADHANSIA XR (methylphenidate ER) capsule ADZENYS ER (amphetamine) suspension ADZENYS XR-ODT (amphetamine) Amphetamine salts, mixed ER (generic Adderall XR) APTENSIO XR (methylphenidate ER) capsule Clonidine ER tablet COTEMPLA XR ODT (methylphenidate ER) DAYTRANA (methylphenidate) patch DEXEDRINE (dextroamphetamine) Spansule Dextroamphetamine ER capsule, solution, tablet DYANAVEL XR (amphetamine) solution EVEKEO (amphetamine) ODT, tablet FOCALIN (dexmethylphenidate) tablet FOCALIN XR (dexmethylphenidate) capsule INTUNIV (guanfacine ER) tablet JORNAY PM (methylphenidate) capsule	*Preferred medications may be approved through AutoPA for indications listed in Table 1 (preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis). Non-preferred medications may be approved for members meeting the following criteria (for Sunosi (solriamfetol) and Wakix (pitolisant), refer to specific criteria listed below): ● Prescription meets indication/age limitation criteria (Table 1) **AND** ● Member meets one of the following: • If member is ≥ 6 years of age, has documented trial and failure‡ with three preferred products in the last 24 months **OR** • If member is 3 –5 years of age, has documented trial and failure‡ with one preferred product in the last 24 months **AND** ● For Daytrana, Methylin solution, Quillichew, Quillivant XR and Dyanavel XR: • One of the trials must include dexmethylphenidate ER, Vyvanse, or Adderall XR AND • Member has a documented difficulty swallowing and is unable to utilize alternative dosing with preferred tablet and capsule formulations. **SUNOSI** (solriamfetol) prior authorization may be approved if member meets the following criteria: ● Member is 18 years of age or older AND ● Member has diagnosis of either narcolepsy or obstructive sleep apnea (OSA) and is experiencing excessive daytime sleepiness AND ● Member does not have end stage renal disease AND ● If Sunosi is being prescribed for OSA, member has 1 month trial of CPAP AND ● Member has trial and failure‡ of modafinil AND armodafinil AND one other agent in stimulant PDL class. **WAKIX** (pitolisant) prior authorization may be approved if member meets the following criteria:

VYVANSE (lisdexamfetamine) capsule	Methamphetamine tablet METHYLIN (methylphenidate) suspension Methylphenidate solution Methylphenidate CD/ER capsule, 18mg, 27mg, 54mg ER tablet, Methylphenidate 36mg ER tablet (generic Concerta) – *all other manufacturers*- MYDAYIS ER (dextroamphetamine/ amphetamine) capsule NUVIGIL (armodafinil) tablet PROCENTRA (dextroamphetamine) solution PROVIGIL (modafinil) tablet QELBREE (viloxazine ER) capsule QUILLICHEW ER (methylphenidate) chewable tablet QUILLIVANT XR (methylphenidate) suspension RELEXXII (methylphenidate ER) tablet RITALIN (methylphenidate) tablet RITALIN LA (methylphenidate ER) capsule STRATTERA (atomoxetine) capsule SUNOSI (solriamfetol) tablet VYVANSE (lisdexamfetamine) chewable tablet WAKIX (pitolisant) tablet ZENZEDI (dextroamphetamine) tablet	• Member is 18 years of age or older **AND** • Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness **AND** • Member does not have end stage renal disease (eGFR <15 mL/minute) **AND** • Member does not have severe hepatic impairment **AND** • Member does not have a history of QT interval prolongation **AND** • Member has trial and failure‡ of modafinil **AND** armodafinil **AND** one other agent in the stimulant PDL class **AND** • Member has been counseled that Wakix may reduce the efficacy of hormonal contraceptives and regarding use an alternative non-hormonal method of contraception during Wakix therapy and for at least 21 days after discontinuing treatment. Maximum Dose (all products): See Table 2 **Exceeding Max Dose:** Prior authorization may be approved for doses that are higher than the listed maximum dose (Table 2) for members meeting the following criteria: • Member is taking medication for indicated use listed in Table 1 **AND** • Member has 30-day trial and failure‡ of three different preferred or non-preferred agents at maximum doses listed in Table 2 **AND** • Documentation of member's symptom response to maximum doses of three other agents is provided **AND** • Member is not taking a sedative hypnotic medication (such as temazepam, triazolam, or zolpidem from the Sedative Hypnotic PDL class). ‡Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Indication and Age Limitations

- Approval for medically accepted indications not listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication.
- Preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval.
- **Bolded drug names are preferred** (subject to preferential coverage changes for brand/generic equivalents)

Drug	Indication/Age
Stimulants–Immediate Release	
Amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
Dextroamphetamine IR (ZENZEDI)	ADHD (Age 3 to≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine solution (PROCENTRA)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Methamphetamine (DESOXYN)	ADHD (Age ≥ 6 years)
methylphenidate IR (generic METHYLIN, RITALIN)	ADHD (Age ≥ 6 years[†]), Narcolepsy (Age ≥ 6 years), OSA. [†]Prior Authorization for members 4-6 years of age with a diagnosis of ADHD may be approved with prescriber attestation to the following: • Member's symptoms have not significantly improved despite adequate behavior interventions AND • Member experiences moderate-to-severe continued disturbance in functioning AND • Prescriber has determined that the potential benefits of starting methylphenidate before the age of 6 years outweigh the potential harm of delaying treatment.
Mixed amphetamine salts IR (generic ADDERALL)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Stimulants –Extended-Release	
Amphetamine ER (ADZENYS XR-ODT and ADZENYS ER suspension)	ADHD (Age ≥ 6 years)
Amphetamine ER (DYANAVEL XR)	ADHD (Age ≥ 6 years)
Mixed-amphetamine salts ER (**ADDERALL XR**)	ADHD (Age ≥ 6 years)
Dexmethylphenidate ER (generic Focalin XR)	ADHD (Age ≥ 6 years)
Dextroamphetamine ER (DEXEDRINE)	ADHD (Age 6 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Dextroamphetamine IR and ER (DEXTROSTAT)	ADHD and Narcolepsy (IR ≥ 3 years, ER ≥ 6 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule**, Vyvanse chewable)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
Methylphenidate ER OROS **(CONCERTA)**	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
Methylphenidate patch (DAYTRANA)	ADHD (Age ≥ 6 years)
Methylphenidate SR (METADATE ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (METADATE CD)	ADHD (Age ≥ 6 years)
Methylphenidate ER (QUILLICHEW ER)	ADHD (Age 6 years to ≤ 65 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (QUILLIVANT XR)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)

Methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (ADHANSIA XR)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years)
Clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
Guanfacine ER (generic INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
Viloxazine ER (QELBREE)	ADHD (Age 6 years to ≤ 17 years)
Wakefulness-promoting Agents	
Armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD (Age ≥ 18 years)
Modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD) (Age ≥ 18 years)
Pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy (Age ≥ 18 years)
Solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA (Age ≥ 18 years)
KEY: **ADHD**–attention-deficit/hyperactivity disorder, **OSA**–obstructive sleep apnea, **SWD**–shift work disorder	

Table 2: Maximum Dose

Drug	Maximum Daily Dose
ADDERALL	60 mg
ADDERALL XR	60 mg
ADHANSIA XR	85 mg
ADZENYS XR ODT ADZENYS ER SUSPENSION	18.8 mg (age 6-12) 12.5 mg (age ≥ 13)
AMPHETAMINE SALTS	40 mg
APTENSIO XR	60 mg
CONCERTA	54 mg (age 6-12) or 72 mg (≥ age 13)
COTEMPLA XR-ODT	51.8 mg
DEXTROAMPHETAMINE ER	60 mg
DAYTRANA	30 mg
DESOXYN	25 mg
DEXEDRINE	60 mg
DEXTROSTAT	60 mg
DYANAVEL XR	20 mg
EVEKEO	60 mg
FOCALIN	20 mg
FOCALIN XR	40 mg
INTUNIV ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
JORNAY PM	100 mg
KAPVAY ER	0.4 mg
METADATE CD	60 mg
METADATE ER	60 mg

METHYLIN	60 mg
METHYLIN ER	60 mg
METHYLIN SUSPENSION	60 mg
METHYLPHENIDATE	60 mg
METHYLPHENIDATE ER	60 mg
MYDAYIS ER	25 mg (age 13-17) or 50 mg (age ≥ 18)
NUVIGIL	250 mg
PROCENTRA	60 mg
PROVIGIL	400 mg
QELBREE	400 mg
QUILLICHEW ER	60 mg
QUILLIVANT XR	60 mg
RITALIN IR	60 mg
RITALIN SR	60 mg
RITALIN LA	60 mg
STRATTERA	100 mg
SUNOSI	150 mg
VYVANSE CAPSULES AND CHEWABLE TABLETS	70 mg
WAKIX	35.6 mg
ZENZEDI	60 mg

Therapeutic Drug Class: **TRIPTANS, DITANS AND OTHER MIGRAINE TREATMENTS - Oral -** *Effective 1/1/2022*

No PA Required (quantity limits may apply)

Eletriptan tablet (generic Relpax)

Naratriptan tablet (generic Amerge)

Rizatriptan tablet, ODT (generic Maxalt)

Sumatriptan tablet (generic Imitrex)

PA Required

Almotriptan tablet

AMERGE (naratriptan) tablet

FROVA (frovatriptan) tablet

Frovatriptan tablet

IMITREX (sumatriptan) tablet

MAXALT/MAXALT MLT (rizatriptan) tablet, ODT

RELPAX (eletriptan) tablet

REYVOW (lasmiditan) tablet

Sumatriptan/Naproxen tablet

TREXIMET (sumatriptan/naproxen) tablet

Non-preferred oral triptan products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, contraindication to therapy or significant drug-drug interaction.

Quantity Limits:

Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Zomig (zolmitriptan)	Max 9 tabs/30 days
Treximet (sumatriptan/naproxen)	Max 9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	Max 6 tabs/30 days
Maxalt (rizatriptan)	Max 12 tabs/30 days
Reyvow (lasmiditan)	Max 8 tabs/30 days

	Zolmitriptan tablet, ODT ZOMIG/ZOMIG ZMT (zolmitriptan) tablet, ODT	

Therapeutic Drug Class: **TRIPTANS, DITANS, AND OTHER MIGRAINE TREATMENTS - Non-Oral -***Effective 1/1/2022*

No PA Required (quantity limits may apply)	**PA Required**	
IMITREX[BNR] (sumatriptan) nasal spray Sumatriptan vial Zolmitriptan nasal spray (*Amneal only)*	IMITREX (sumatriptan) cartridge, pen injector ONZETRA XSAIL (sumatriptan) nasal powder Sumatriptan cartridge, nasal spray, pen injector, vial TOSYMRA (sumatriptan) nasal spray ZEMBRACE SYMTOUCH (sumatriptan) auto-injector Zolmitriptan nasal spray (all other manufacturers) ZOMIG (zolmitriptan) nasal spray	**Zembrace Symtouch injection**, **Tosymra nasal spray**, or **Onzetra Xsail nasal powder** may be approved for members who have trialed and failed one preferred non-oral triptan products AND two oral triptan agents with different active ingredients. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, significant drug-drug interaction, or documented inability to take alternative dosage form. All other non-preferred products may be approved for members who have trailed and failed one preferred non-oral triptan product AND one preferred oral triptan product. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions, documented inability to tolerate dosage form. **Quantity Limits:**

Imitrex (sumatriptan) injection	Max 4 injectors / 30 days
Imitrex (sumatriptan) nasal spray	Max 6 inhalers / 30 days
Onzetra Xsail (sumatriptan) nasal powder	Max 16 nosepieces / 30 days
Tosymra (sumatriptan) nasal spray	Max 12 nasal spray devices / 30 days
Zembrace Symtouch (sumatriptan) injection	Max 36mg / 30 days
Zomig (zolmitriptan) nasal spray	Max 6 inhalers / 30 days

V. Dermatological

Therapeutic Drug Class: **ACNE AGENTS– Topical -***Effective 7/1/2021*

No PA Required (if age and diagnosis criteria are met*)	**PA Required**	
Brand/generic changes effective 8/10/21 *ACZONE (dapsone) gel *Adapalene gel *Adapalene/benzoyl peroxide (generic Epiduo) *Clindamycin phosphate solution, medicated swab	ACANYA (clindamycin/benzoyl peroxide) gel, pump ACZONE (dapsone) pump Adapalene cream, gel pump, solution AKLIEF (trifarotene) cream AKTIPAK (erythromycin/benzoyl peroxide) ALTRENO (tretinoin) lotion AMZEEQ (minocycline) foam	Authorization for all acne agents prescribed solely for cosmetic purposes will not be approved. Preferred topical clindamycin and erythromycin products may be approved by AutoPA verification of ICD-10 diagnosis code for acne vulgaris, psoriasis, cystic acne, comedonal acne, disorders of keratinization, neoplasms, folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications may be considered following clinical prior authorization review by a call center pharmacist. All other preferred topical acne agents may be approved if meeting the following criteria: • For members > 25 years of age, may be approved following prescriber verification that the medication is not being utilized for cosmetic purposes AND prescriber verification that the indicated use is for acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal

*Clindamycin/benzoyl peroxide gel jar (generic Benzaclin) *Clindamycin/benzoyl peroxide (generic Duac) *Dapsone gel *DIFFERIN[BNR] (adapalene) gel pump *Erythromycin solution *Erythromycin / Benzoyl peroxide *Sulfacetamide sodium suspension *RETIN-A[BNR] (tretinoin) cream, gel	ARAZLO (tazarotene) lotion ATRALIN (tretinoin) gel AVITA (tretinoin) AZELEX (azelaic acid) cream BENZACLIN (clindamycin/benzoyl peroxide) (all products) BENZAMYCIN (erythromycin) gel CLEOCIN (clindamycin) gel, lotion, pledgets, solution CLINDACIN (clindamycin phosphate) CLINAGEL (clindamycin phosphate) gel Clindamycin phosphate gel, lotion, foam Clindamycin/tretinoin Dapsone pump DIFFERIN (adapalene) cream, lotion EPIDUO FORTE (adapalene/benzoyl peroxide) ERY/ERYGEL (erythromycin/ethanol) Erythromycin gel, med swab EVOCLIN (clindamycin) foam FABIOR (tazarotene) foam KLARON (sulfacetamide) suspension NEUAC (clindamycin/benzoyl peroxide) gel ONEXTON (clindamycin/benzoyl peroxide) RETIN-A MICRO (tretinoin) (all products)	acne. These medications are only eligible for prior authorization approval for the aforementioned diagnoses. • For members ≤ 25 years of age, may be approved for a diagnosis of acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis code related to the indicated use of the medication. Non-preferred topical products may be approved for members meeting all of the following criteria: • Member has trialed/failed three preferred topical products with different mechanisms (such as tretinoin, antibiotic). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND • Prescriber verification that the medication is being prescribed for one of the following diagnoses: acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne.

	ROSULA (sulfacetamide sodium/ sulfur) cloths, wash Sulfacetamide sodium cleansing gel, lotion, shampoo, wash Sulfacetamide sodium/ sulfur cleanser, cream, pad, suspension, wash SUMADAN (sulfacetamide sodium/sulfur) kit, wash SUMAXIN (sulfacetamide sodium/sulfur kit, pads, suspension, wash Tazarotene cream TAZORAC (tazarotene) cream, gel Tretinoin (all products) Tretinoin microspheres (all products) ZIANA (clindamycin/tretinoin) gel	
Therapeutic Drug Class: **ACNE AGENTS– ORAL ISOTRETINOIN** -*Effective 7/1/2021*		
PA Required for all agents		*Preferred product criteria update (effective 1/1/22):* Preferred products may be approved for adults and children ≥ 12 years of age for treating severe acne vulgaris or for treating moderate acne vulgaris in members unresponsive to conventional therapy. Non-preferred products may be approved for members meeting the following: ● Member has trialed/failed two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND ● Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy.
AMNESTEEM capsule CLARAVIS capsule	ABSORICA capsule ABSORICA LD capsule Isotretinoin capsule MYORISAN capsule ZENATANE capsule	
Therapeutic Drug Class: **ANTI-PSORIATICS - Oral** -*Effective 1/1/2022*		
No PA Required	**PA Required**	Prior authorization for non-preferred oral agents may be approved with failure of two preferred anti-psoriatic agents, one of which must be a preferred oral agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction.
Acitretin capsule	Methoxsalen capsule OXSORALEN-ULTRA (methoxsalen) capsule SORIATANE (acitretin) capsule	

Therapeutic Drug Class: **ANTI-PSORIATICS -Topical** -*Effective 1/1/2022*		
No PA Required Calcipotriene solution DOVONEX [BNR] (calcipotriene) cream TACLONEX SCALP [BNR] (calcipotriene/betamethasone) suspension TACLONEX [BNR] (calcipotriene/betamethasone) ointment	**PA Required** Calcipotriene cream, foam, ointment Calcipotriene/betamethasone dipropionate ointment, suspension (generic Taclonex) Calcitriol ointment DUOBRII (halobetasol/tazarotene) lotion ENSTILAR (calcipotriene/betamethasone) foam SORILUX (calcipotriene) foam VECTICAL (calcitriol) ointment	Prior authorization for non-preferred topical agents may be approved with failure of two preferred topical agents. If non-preferred topical agent being requesting is a combination product, trial of two preferred agents must include a preferred combination agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction. Preferred and non-preferred products that contain a corticosteroid ingredient (such as betamethasone) will be limited to 4 weeks of therapy. Continued use will require one week of steroid-free time in between treatment periods. Members with >30% of their body surface area affected may not use Enstilar (calcipotriene/betamethasone DP) foam or Taclonex (calcipotriene/betamethasone DP) ointment products as safety and efficacy have not been established.
Therapeutic Drug Class: **IMMUNOMODULATORS, TOPICAL** – *Effective 1/1/2022*		
No PA Required ELIDEL[BNR] (pimecrolimus) cream PROTOPIC [BNR] (tacrolimus) ointment	**PA Required** OPZELURA (ruxolitinib) Pimecrolimus cream Tacrolimus ointment	Non-preferred topical immunomodulator products may be approved for atopic dermatitis following adequate trial and failure‡ of one prescription topical corticosteroid AND two preferred agents. ‡Failure is defined as a lack of efficacy with one month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. For members under 18 years of age, must be prescribed by or in consultation with a dermatologist or allergist/immunologist.
Therapeutic Drug Class: **ANTINEOPLASTIC AGENTS, TOPICAL** – *Effective 7/1/2021*		
No PA Required (unless indicated*) *Diclofenac 3% gel (generic Solaraze) Fluorouracil 5% cream (generic Efudex) Fluorouracil 2%, 5% solution	**PA Required** CARAC (fluorouracil) EFUDEX (fluorouracil) Fluorouracil 0.5% cream (generic Carac) PANRETIN (alitretinoin) PICATO (ingenol mebutate) TARGRETIN (bexarotene) TOLAK (fluorouracil)	***Diclofenac 3% gel** (generic Solaraze) may be approved if the member has a diagnosis of actinic keratosis (AK). **TARGRETIN** (bexarotene) gel or **VALCHLOR** (mechlorethamine) gel may be approved for members who meet the following criteria: • Member is ≥ 18 years of age **AND** • Member has been diagnosed with Stage IA or IB cutaneous T-cell lymphoma (CTCL) **AND** • Member has refractory or persistent CTCL disease after other therapies OR has not tolerated other therapies • Member and partners have been counseled on appropriate use of contraception Non-preferred agents may be approved for members who have failed an adequate trial of all preferred products FDA-approved for that indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

	VALCHLOR (mechlorethamine)	
Therapeutic Drug Class: **ROSACEA AGENTS** -*Effective 7/1/2021*		
No PA Required FINACEA[BNR] (azelaic acid) gel METROGEL[BNR] (metronidazole) Metronidazole cream, lotion	**PA Required** Azelaic acid gel *Doxycycline monohydrate DR capsule (generic Oracea) FINACEA (azelaic acid) foam METROCREAM (metronidazole) Metronidazole gel MIRVASO (brimonidine) NORITATE (metronidazole) *ORACEA (doxycycline monohydrate DR) capsule RHOFADE (oxymetazoline) ROSADAN (metronidazole) SOOLANTRA (ivermectin) ZILXI (minocycline)	Prior authorization for non-preferred products in this class may be approved if member meets the following criteria: ● Member has a diagnosis of persistent (non-transient) facial erythema with inflammatory papules and pustules due to rosacea AND ● Prescriber attests that medication is not being used solely for cosmetic purposes AND ● Member has tried and failed two preferred agents of different mechanisms of action (Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects) *__Oracea__ (doxycycline monohydrate DR) may be approved if the following criteria are met: ● Member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months. Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member has history of an adequate trial/failure (8 weeks) of 2 other preferred agents (oral or topical). Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member is ≥ 18 years of age and has been diagnosed with rosacea with inflammatory lesions (papules and pustules)
Therapeutic Drug Class: **TOPICAL STEROIDS** – *Effective 1/1/2022*		
Low potency		
No PA Required Hydrocortisone (Rx) cream, ointment, lotion DERMA-SMOOTHE-FS [BNR] (fluocinolone) 0.01% oil Desonide 0.05% cream, ointment Fluocinolone 0.01% cream	**PA Required** Alclometasone 0.05% cream, ointment CAPEX (fluocinolone) 0.01% shampoo DESONATE (desonide) 0.05% gel Desonide 0.05% lotion	Non-preferred Low Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Low Potency class (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

	Fluocinolone 0.01% body oil, 0.01% scalp oil, 0.01% solution SYNALAR (fluocinolone) 0.01% solution SYNALAR TS (fluocinolone/skin cleanser) Kit TEXACORT (hydrocortisone) 2.5% solution	
Medium potency		
No PA Required Betamethasone dipropionate 0.05% lotion Betamethasone valerate 0.1% cream, ointment Fluocinolone 0.025% cream Fluticasone 0.05% cream, 0.005% ointment Mometasone 0.1% cream, 0.1% ointment, 0.1% solution Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion	**PA Required** BESER (fluticasone) lotion, emollient kit Betamethasone dipropionate 0.05% cream Betamethasone valerate 0.1% lotion, 0.12% foam Clocortolone 0.1% cream, cream pump CLODERM (clocortolone) 0.1% cream, cream pump CUTIVATE (fluticasone) 0.05% cream, lotion DERMATOP (prednicarbate) 0.1% ointment Diflorasone 0.05% cream Fluocinolone 0.025% ointment Fluocinonide-E 0.05% cream Flurandrenolide 0.05% cream, lotion, ointment Fluticasone 0.05% lotion Hydrocortisone butyrate 0.1% cream, lotion, solution, ointment, lipid/lipocream Hydrocortisone valerate 0.2% cream, ointment KENALOG (triamcinolone) spray LOCOID (hydrocortisone butyrate) 0.1% lotion	Non-preferred Medium Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Medium Potency class (failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

	LOCOID LIPOCREAM (hydrocortisone butyrate-emollient) 0.1% cream LUXIQ (betamethasone valerate) 0.12% foam PANDEL (hydrocortisone probutate) 0.1% cream Prednicarbate 0.1% cream, ointment PSORCON (diflorasone) 0.05% cream SYNALAR (fluocinolone) 0.025% cream/kit, ointment/kit Triamcinolone 0.147 mg/gm spray	
High potency		
No PA Required (*unless exceeds duration of therapy) *Betamethasone dipropionate/propylene glycol (augmented) 0.05% cream *Fluocinonide 0.05% cream, 0.05% gel, 0.05% solution, 0.05% ointment *Triamcinolone acetonide 0.5% cream, 0.5% ointment	**PA Required** Amcinonide 0.1% cream, lotion APEXICON-E (diflorasone/emollient) 0.05% cream Betamethasone dipropionate 0.05% ointment Desoximetasone 0.05%, 0.25% cream, 0.05% gel, 0.05%, 0.25% ointment Diflorasone 0.05% ointment Halcinonide 0.1% cream HALOG (halcinonide) 0.1% cream, ointment, solution TOPICORT (desoximetasone) 0.05%, 0.25% cream, 0.05% gel, 0.05%, 0.25% ointment	Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). *All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.
Very high potency		
No PA Required (unless exceeds duration of therapy*) *Betamethasone dipropionate/propylene glycol (augmented) 0.05% ointment	**PA Required** Betamethasone dipropionate/propylene glycol (augmented) 0.05% gel, 0.05% lotion BRYHALI (halobetasol) 0.01% lotion Clobetasol emollient/emulsion 0.05% cream, foam Clobetasol 0.05% lotion, foam, spray, shampoo	Non-preferred Very High Potency topical corticosteroids may be approved following adequate trial and failure of clobetasol propionate in the same formulation as the product being requested (if the formulation of the requested non-preferred product is not available in preferred clobetasol product options, then trial and failure of any preferred clobetasol product formulation will be required). Failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions.

*Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution *Fluocinonide 0.1% cream	CLOBEX (clobetasol) 0.05% spray, 0.05% shampoo CLODAN (clobetasol) 0.05% shampoo Desoximetasone 0.25% spray DIPROLENE (betamethasone dipropionate/propylene glycol, augmented) 0.05% ointment Halobetasol 0.05% cream, foam, ointment IMPEKLO (clobetasol) 0.05% lotion LEXETTE (halobetasol) 0.05% foam OLUX (clobetasol) 0.05% foam OLUX-E (clobetasol) 0.05% foam TEMOVATE (clobetasol) 0.05% cream, ointment TOPICORT (desoximetasone) 0.25% spray TOVET EMOLLIENT (clobetasol) 0.05% foam ULTRAVATE (halobetasol) 0.05% lotion VANOS (fluocinonide) 0.1% cream	*All Very High Potency topical corticosteroids will require prior authorization beyond 2 weeks of therapy. If clobetasol propionate shampoo is being used to treat plaque psoriasis, then prior authorization will be required beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

VI. Endocrine

Therapeutic Drug Class: **ANDROGENIC AGENTS, Topical, Injectable, Oral** -*Effective 7/1/2021*

PA Required for all agents in this class		
ANDRODERM (testosterone) patch ANDROGEL (testosterone) gel 1.62% pump[BNR] ANDROGEL (testosterone) gel packet[BNR] Testosterone cypionate IM injection	ANDROID (methyltestosterone) capsule DEPO-TESTOSTERONE (testosterone cypionate) IM injection FORTESTA (testosterone) gel JATENZO (testosterone undecanoate) capsules METHITEST (methyltestosterone) tablet	<u>Hypogonadotropic or Primary Hypogonadism (may be secondary to Klinefelter Syndrome):</u> Preferred products may be approved for members meeting the following: • Member is a male patient ≥ 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome (all other diagnoses will require manual review) AND • Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND • Member does not have a diagnosis of breast or prostate cancer AND

Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.	Methyltestosterone capsule NATESTO (testosterone) nasal spray TESTIM (testosterone) gel TESTRED (methyltestosterone) capsule Testosterone gel, packet, pump Testosterone enanthate IM injection VOGELXO (testosterone) XYOSTED (testosterone enanthate) SC injection	• If the member is > 40 years of age, has prostate-specific antigen (PSA) < 4 ng/mL or has no palpable prostate nodule AND • Member has baseline hematocrit < 50% Reauthorization Criteria (requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria): • Member is a male patient ≥ 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome AND • Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of the normal reference range AND • Member does not have a diagnosis of breast or prostate cancer AND • Member has a hematocrit < 54% Gender Transition/Affirming Hormone Therapy: Preferred androgenic drugs may be approved for members meeting the following: 1. Female sex assigned at birth > 16 years of age AND 2. Is undergoing female to male transition AND 3. Has a negative pregnancy test prior to initiation AND 4. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy. Non-Preferred Products: Non-preferred **topical** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations. Non-preferred **injectable** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug. Prior authorization for **oral** androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent AND testosterone cypionate injection. ‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome).

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">Therapeutic Drug Class: BONE RESORPTION SUPPRESSION AND RELATED AGENTS -Effective 10/1/2021</td></tr>
<tr><td colspan="3">Bisphosphonates</td></tr>
<tr><td>No PA Required

Alendronate tablet, solution

Ibandronate tablet</td><td>PA Required

ACTONEL (risedronate) tablet

ATELVIA (risedronate) tablet

BONIVA (ibandronate) tablet

FOSAMAX (alendronate) tablet

FOSAMAX plus D (alendronate/vit D) tablet

Risedronate tablet</td><td>Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 AND no history of low trauma or fragility fracture.</td></tr>
<tr><td colspan="3">Non-Bisphosphonates</td></tr>
<tr><td></td><td>PA Required

Calcitonin salmon nasal spray

FORTEO (teriparatide) SC pen

Raloxifene tablet

Teriparatide SC pen

TYMLOS (abaloparatide) SC pen</td><td>CALCITONIN SALMON (nasal) may be approved if the member meets the following criteria:
● Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less) AND
● Has trial and failure of preferred bisphosphonate for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) OR
● Member cannot swallow solid oral dosage forms or has a feeding tube.
Quantity limit: One spray daily

RALOXIFENE may be approved if the member meets the following criteria:
● Diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) AND
● Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
Maximum dose: 60mg daily

FORTEO (teriparatide) or generic teriparatide may be approved if the member meets the following criteria:
● Member has one of the following diagnoses:
● Osteoporosis, (BMD T-scores of -2.5 or less) primary or hypogonadal in men
● Osteoporosis due to corticosteroid use
● Postmenopausal osteoporosis
AND</td></tr>
</table>

		• Member is post-menopausal with very high risk for fracture* OR member has history of trial and failure of a preferred bisphosphonate for one year. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • For brand FORTEO, member has trialed and failed generic teriparatide. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years Maximum dose: 20mcg daily **TYMLOS** (abaloparatide) may be approved if the member meets the following criteria: • Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND** • Member is post-menopausal with very high risk for fracture* OR member has history of trial and failure of a preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** • Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years. Maximum dose: 80 mcg daily All other non-preferred non-bisphosphonates may be approved for members who have failed treatment with one preferred bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, unable to use oral therapy, intolerable side effects, or significant drug-drug interaction. *Members at very high risk for fracture: Members will be considered at very high risk for fracture if they meet <u>one</u> of the following: • A history of fracture within the past 12 months **OR** • Fractures experienced while receiving guideline-supported osteoporosis therapy **OR** • A history of multiple fractures **OR** • A history of fractures experienced while receiving medications that cause skeletal harm (such as long-term glucocorticoids) **OR** • A very low T-score (less than -3.0) **OR** • A high risk for falls or a history of injurious falls **OR** • A very high fracture probability by FRAX (> 30% for a major osteoporosis fracture or > 4.5% for hip fracture) *Note: Prior authorization criteria for Prolia (denosumab) and other injectable bone resorption and related agents are listed on Appendix P.*
Therapeutic Drug Class: **CONTRACEPTIVES - Oral** *Effective 10/1/2021*		

Effective 01/14/22, oral contraceptive products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

No PA Required		PA Required	
No PA Required **Monophasic 28**:	**No PA Required** **Biphasic**:	All other rebateable oral contraceptive products are non-preferred	Non-preferred oral contraceptive products may be approved if member fails one-month trial with four preferred agents OR if preferred products with medically necessary ingredients and/or doses are unavailable. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction. Prescription Contraceptive Products 12-Month Supply: Initial fills of oral contraceptive products may be dispensed for up to a three-month supply to establish tolerance (lack of adverse events). If the prescribed medication is tolerated for at least three months of therapy, subsequent fills of that medication will be eligible to be filled for up to a twelve-month supply.
Altavera 28 0.15-30 Apri 28 0.15-30 Aubra 28 0.1-20 Aubra EQ-28 0.1-20 Aviane 28 0.1-20 Balziva 28 0.4-35 Cryselle 28 0.3-30 Cyclafem 28 1-35 Dasetta 28 1-35 Drospirenone-EE 28 0.3-30 Drospirenone-EE-Levomefolate 28 3-20 Drospirenone-EE-Levomefolate 28 3-30 Elinest 28 0.3-30 Enskyce 28 0.15-30 Estarylla 28 0.25-35 Ethynodiol-EE 28 1-50 Falmina 28 0.1-20 Femynor 28 0.25-35 Isibloom 28 0.15-30 Juleber 28 0.15-30 Kelnor 28 1-35 Kurvelo 28 0.15-30 Larissia 28 0.1-20 Lessina 28 0.1-20 Levonorgestrel-EE 28 0.1-20 Levonorgestrel-EE 28 0.15-30 Levora 28 0.15-30 Lillow 28 0.15-30 Low-Ogestrel 28 0.3-30 Lutera 28 0.1-20 Marlissa 28 0.15-30 Mili 28 0.25-35 Mono-Linyah 28 0.25-35 Necon 28 0.5-35 Norgestimate-EE 28 0.25-35 Nortrel 28 0.5-35 Nortrel 28 1-35 Ocella 28 3-30	Azurette 28 Bekyree 28 Cyred 28 Desogestrel-EE 28 Emoquette 28 Kariva 28 Lo Loestrin FE 28 1-10 Mircette 28 Viorele 28 **Triphasic**: Alyacen 7-7-7 28 Caziant 7-7-7 28 Cyclafem 7-7-7 28 Dasetta 7-7-7 28 Enpresse 28 Levonest 28 Levonorgestrel-EE Triphasic 28 Norgestimate-EE 0.18-0.215-0.25/0.025 Norgestimate-EE 0.18-0.215-0.25/0.035 Nortrel Triphasic 28 Pirmella 7-7-7 Tri-Estarylla 28 Tri Femynor 28 Tri-Linyah 28 Tri-Lo-Estarylla 28 Tri-Lo-Marzia 28 Tri-Lo-Mini 28 Tri-Lo-Sprintec 28 Tri-Sprintec 28 Tri-Vylibra Lo 28 Velivet 7-7-7 28 **Extended Cycle**: Amethia 91 0.03 – 0.15 – 0.01 Ashlyna 91 0.15-10-30 Iclevia 91 0.15-30 Introvale 91 0.15-30 Jolessa 91 0.15-30 Levonorgestrel-EE 91 0.1-10-20 Levonorgestrel-EE 91 0.15-0.03		

Orsythia 28 1-20 Philith 28 0.4-35 Pirmella 28 1-35 Portia 28 0.15-30 **No PA Required** Previfem 28 0.25-35 Sprintec 28 0.25-35 Sronyx 28 0.1-20 Syeda 28 3-30 Vienva 28 0.1-20 Vyfemla 28 0.4-35 Wera 28 0.5-35 **Monophasic 21:** Hailey 21 1.5-30 Junel 21 1-20 Junel 21 1.5-30 Larin 21 1-20 Larin 21 1.5-30 Norethindrone-EE 21 1-20 Nortrel 21 1-35 **Norethindrone Only**: Camila 28 0.35 Deblitane 28 0.35 Errin 28 0.35 Heather 28 0.35 Jencycla 28 0.35 Jolivette 28 0.35 Lyza 28 0.35 Norethindrone 28 0.35 Norlyda 28 0.35 Sharobel 28 0.35 *EE – Ethinyl Estradiol	Levonorgestrel-EE 91 0.15-0.03-0.01 Setlakin 91 0.15-30 **Continuous Cycle**: **No PA Required** Aurovela FE 1-20 Aurovela FE 1.5-30 Blisovi FE 1-20 Blisovi FE 1.5-30 Camrese Lo 1-20 Gianvi 3-20 Hailey FE 1.5-30 Hailey FE 1-20 Jasmiel 3-20 Junel FE 1-20 Junel FE 1.5-30 Junel FE 24 1-20 Larin FE 1-20 Larin FE 24 1-20 Larin FE 1.5-30 LoJaimiess 1-20 Loryna 3-20 Microgestin FE 1-20 Nikki 3-20 Norethindrone-EE-FE 24 1-20 Norethindrone-EE-FE 1-20 Tarina FE 24 1-20 Tarina FE 1-20 Tarina FE 1-20 EQ *EE – Ethinyl Estradiol		

Therapeutic Drug Class: **CONTRACEPTIVES - Topical** *Effective 10/1/2021*

Effective 01/14/22, topical contraceptive patch products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

No PA Required	**PA Required**	
ANNOVERA (segesterone acetate/EE) vaginal ring NUVARING[BNR] (etonorgestrel/EE) vaginal ring	Etonorgestrel/EE vaginal ring PHEXXI (lactic acid/citric/potassium) vaginal gel TWIRLA (levonorgestrel/EE) TD patch	Non-preferred topical contraceptive products may be approved following a trial and failure of one preferred topical contraceptive product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **PHEXXI** (lactic acid/citric acid/potassium) vaginal gel may be approved for members who meet the following criteria: • Medication is being prescribed for the prevention of pregnancy **AND**

XULANE (norelgestromin/EE) TD patch *EE – Ethinyl Estradiol	ZAFEMY (norelgestromin/EE) TD patch	• Member is unable to use any of the following methods of contraception due to failure, contraindication, intolerance, or preference: o Injection (such as medroxyprogesterone acetate) o Oral Contraceptive o Transdermal Patch o Vaginal Contraceptive Ring o Diaphragm o Cervical Cap **AND** • PHEXXI (lactic acid/citric acid/potassium) is not being prescribed concomitantly with a vaginal ring product, **AND** • Provider attests that member has been counseled regarding a higher rate of pregnancy prevention with the use of other methods of contraception (such as injection, oral contraception, transdermal patch, vaginal ring) as compared to PHEXXI. <u>Prescription Contraceptive Products 12-Month Supply:</u> Initial fills of patch and vaginal ring contraceptive products may be dispensed for up to a three-month supply to establish tolerance (lack of adverse events). If the prescribed medication is tolerated for at least three months of therapy, subsequent fills of that medication will be eligible to be filled for up to a twelve-month supply. *Note: Depot and IUD formulations are billed through the medical benefit.*
Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, INSULINS**- *Effective 10/1/2021*		
Rapid-Acting		
No PA Required HUMALOG (insulin lispro) 100 U/mL cartridge, vial, KwikPen, pen HUMALOG Jr. (insulin lispro) KwikPen NOVOLOG (insulin aspart) cartridge, vial, FlexTouch pen	**PA Required** ADMELOG (insulin lispro) Solostar pen, vial AFREZZA (regular insulin) cartridge, unit APIDRA (insulin glulisine) Solostar pen, vial FIASP (insulin aspart) FlexTouch pen, PenFill, vial HUMALOG (insulin lispro) 200 U/mL pen Insulin aspart cartridge, pen, vial	Non-preferred products may be approved following trial and failure of treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects). **Afrezza** (human insulin) may be approved if meeting the following criteria: • Member is 18 years or older AND • Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, or angioedema] or intolerable side effects) AND • Member must not have chronic lung disease such as COPD or asthma AND • If member has type 1 diabetes, must use in conjunction with long-acting insulin AND • Member must not be a smoker

	Insulin lispro pen, vial Insulin lispro, Jr. Kwikpen LYUMJEV (insulin lispro-aabc) Kwikpen, vial	
Short-Acting		
No PA Required HUMULIN R U-100 (insulin regular) vial (OTC) HUMULIN R U-500 (insulin regular) concentrated vial, Kwikpen NOVOLIN R U-100 (insulin regular) FlexPen (OTC)	**PA Required** HUMULIN R U-100 (insulin regular) KwikPen (OTC) NOVOLIN R U-100 (insulin regular) vial (OTC)	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
Intermediate-Acting		
No PA Required HUMULIN N U-100 (insulin NPH) vial (OTC) NOVOLIN N U-100 (insulin NPH) FlexPen (OTC)	**PA Required** HUMULIN N U-100 (insulin NPH) KwikPen (OTC) NOVOLIN N U-100 (insulin NPH) vial (OTC)	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
Long-Acting		
No PA Required LANTUS (insulin glargine) vial, Solostar LEVEMIR (insulin detemir) vial, FlexTouch	**PA Required** BASAGLAR (insulin glargine) KwikPen SEMGLEE (insulin glargine) pen, vial TOUJEO (insulin glargine) Solostar TOUJEO MAX (insulin glargine) Solostar TRESIBA (insulin degludec) FlexTouch, vial	Non-preferred products may be approved if the member has failed treatment with Levemir AND Lantus (failure is defined as allergy or intolerable side effects).
Mixtures		

No PA Required	PA Required	
HUMALOG MIX 50/50 Kwikpen, vial HUMALOG MIX 75/25 Kwikpen, vial HUMULIN 70/30 (OTC) Kwikpen, vial NOVOLOG MIX 70/30 FlexPen, vial	Insulin aspart protamine/insulin aspart 70/30 FlexPen, vial (generic Novolog Mix) Insulin lispro protamine/insulin lispro 75/25 Kwikpen, vial (generic Humalog Mix) NOVOLIN 70/30 FlexPen, vial (OTC)	Non-preferred products may be approved if the member has failed treatment with two of the preferred products (failure is defined as: allergy or intolerable side effects).
Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, NON- INSULINS**- *10/1/2021*		
Amylin		
	PA Required	**SYMLIN** (pramlintide) may be approved following trial and failure of metformin AND trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) following 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for Symlin (pramlintide) products for members with a diagnosis of Type 1 diabetes without requiring trial and failure of other products. Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.
	SYMLIN (pramlintide) pen	
Biguanides		
No PA Required	**PA Required**	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Liquid metformin may be approved for members who meet one of the following: • Member is under the age of 12 with a feeding tube **OR** • Prescriber confirms that member has difficulty swallowing
Metformin 500mg, 850mg, 1000mg tablets Metformin ER 500mg, 750mg tablets (generic Glucophage XR)	FORTAMET (metformin) GLUCOPHAGE (metformin) GLUCOPHAGE XR (metformin XR) GLUMETZA ER (metformin) Metformin ER (generic Fortamet, Glumetza) RIOMET (metformin) solution RIOMET ER (metformin) suspension	
Dipeptidyl Peptidase-4 Enzyme inhibitors (DPP-4is)		
***Must meet eligibility criteria**	**PA Required**	

<table>
<tr>
<td>*JANUVIA (sitagliptin) tablet

*TRADJENTA (linagliptin) tablet</td>
<td>Alogliptin tablet

NESINA (alogliptin) tablet

ONGLYZA (saxagliptin) tablet</td>
<td>*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

<u>Maximum Dose:</u>
Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

<table>
<tr><th>DPP4</th><th>FDA-Approved Max Dose</th></tr>
<tr><td>Alogliptin (generic Nesina)</td><td>25 mg/day</td></tr>
<tr><td>Januvia (sitagliptin)</td><td>100 mg/day</td></tr>
<tr><td>Nesina (alogliptin)</td><td>25 mg/day</td></tr>
<tr><td>Onglyza (saxagliptin)</td><td>5 mg/day</td></tr>
<tr><td>Tradjenta (linagliptin)</td><td>5 mg/day</td></tr>
</table>
</td>
</tr>
<tr><td colspan="3">DPP-4 Inhibitors – Combination with Metformin</td></tr>
<tr>
<td>*Must meet eligibility criteria

*JANUMET (sitagliptin/metformin)

*JANUMET XR (sitagliptin/metformin)</td>
<td>PA Required

Alogliptin/metformin

JENTADUETO (linagliptin/metformin)

JENTADUETO XR (linagliptin/metformin)

KAZANO (alogliptin/metformin)

KOMBIGLYZE (saxagliptin/metformin)</td>
<td>*Approval for preferred combination agent products require a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months AND have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.</td>
</tr>
<tr><td colspan="3">Glucagon-like Peptide-1 Receptor Agonists (GLP-1 Analogues)</td></tr>
<tr>
<td>*Must meet eligibility criteria

*BYETTA (exenatide)

*TRULICITY (dulaglutide)

*VICTOZA (liraglutide)</td>
<td>PA Required

ADLYXIN (lixisenatide)

BYDUREON BCISE (exenatide ER)

OZEMPIC (semaglutide)</td>
<td>* Preferred products may be approved for members with a diagnosis of type 2 diabetes following a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred products may be approved for members with a diagnosis of type 2 diabetes following trial and failure of a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects,</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>RYBELSUS (semaglutide)</td>
<td>limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction.

<u>Maximum Dose:</u>
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

<table>
<tr><th colspan="2">Table 1: GLP-1 Analogue Maximum Dose</th></tr>
<tr><td>Adlyxin (lixisenatide)</td><td>20mcg per day</td></tr>
<tr><td>Bydureon BCISE (exenatide)</td><td>2mg weekly</td></tr>
<tr><td>Byetta (exenatide)</td><td>20mcg per day</td></tr>
<tr><td>Ozempic (semaglutide)</td><td>1mg weekly</td></tr>
<tr><td>RYBELSUS (semaglutide)</td><td>14 mg daily</td></tr>
<tr><td>Trulicity (dulaglutide)</td><td>4.5mg weekly</td></tr>
<tr><td>Victoza (liraglutide)</td><td>1.8mg per day</td></tr>
</table>

Note: Authorization for GLP-1 analogues prescribed solely for weight loss will not be approved.</td>
</tr>
<tr>
<td colspan="3">Other Hypoglycemic Combinations</td>
</tr>
<tr>
<td></td>
<td>PA Required

Alogliptin/pioglitazone tablet

AVANDARYL (rosiglitazone/glimepiride)

DUETACT (pioglitazone/glimepiride)

Glipizide/metformin tablet

GLUCOVANCE (glyburide/metformin)

Glyburide/metformin tablet

GLYXAMBI (empagliflozin/linagliptin)

METAGLIP (glipizide/metformin)

OSENI (alogliptin/pioglitazone)

Pioglitazone/glimepiride

QTERN (dapagliflozin/saxagliptin)</td>
<td>Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).</td>
</tr>
</table>

	SOLIQUA (insulin glargine/lixisenatide) pen STEGLUJAN (ertugliflozin/sitagliptin) TRIJARDY XR (empagliflozin/linagliptin/metformin) XULTOPHY (insulin degludec/liraglutide) pen	
Meglitinides		
	PA Required Nateglinide PRANDIN (repaglinide) Repaglinide STARLIX (nateglinide)	Non-preferred products may be approved for members who have failed treatment with one sulfonylurea. Failure is defined as: lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.
Meglitinides Combination with Metformin		
	PA Required Repaglinide/metformin	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.
Sodium-Glucose Cotransporter 2 inhibitors (SGLT-2is)		
No PA Required FARXIGA (dapagliflozin) INVOKANA (canagliflozin) JARDIANCE (empagliflozin)	**PA Required** STEGLATRO (ertugliflozin)	Non-preferred products may receive approval following trial and failure with two preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction. FARXIGA (dapagliflozin), INVOKANA (canagliflozin) and JARDIANCE (empagliflozin) are contraindicated in members on dialysis. STEGLATRO (ertugliflozin) therapy is not recommended when eGFR is persistently 30 to less than 60 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis. <u>Maximum Dose:</u> Prior authorization is required for all products exceeding maximum dose listed in product package labeling.
SGLT-2 Inhibitors Combination with Metformin		
No PA Required INVOKAMET (canagliflozin/metformin)	**PA Required** SEGLUROMET (ertugliflozin/metformin)	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

INVOKAMET XR (canagliflozin/metformin) XIGDUO XR (dapagliflozin/metformin)	SYNJARDY (empagliflozin/metformin) SYNJARDY XR (empagliflozin/metformin)	INVOKAMET, INVOKAMET XR, SYNJARDY, SYNJARDY XR and XIGDUO XR are contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis. SEGLUROMET therapy is not recommended when eGFR is persistently 30 to less than 60 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.
Thiazolidinediones (TZDs)		
No PA Required Pioglitazone	**PA Required** ACTOS (pioglitazone) AVANDIA (rosiglitazone)	Non-preferred agents may be approved following trail and failure of metformin AND trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.
Thiazolidinediones Combination with Metformin		
	PA Required ACTOPLUS MET (pioglitazone/metformin) ACTOPLUS MET XR (pioglitazone/metformin) Pioglitazone/metformin	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.
Therapeutic Drug Class: **ESTROGEN AGENTS** -*Effective 10/1/2021*		
No PA Required	**PA Required**	Non-preferred parenteral estrogen agents may be approved with trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Non-preferred oral estrogen agents may be approved with trial and failure of one preferred oral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Non-preferred transdermal estrogen agents may be approved with trial and failure of two preferred transdermal agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Parenteral		
DELESTROGEN**BNR** (estradiol valerate) vial DEPO-ESTRODIOL (estradiol cypionate) vial	Estradiol valerate vial	
Oral/Transdermal		
CLIMARA**BNR** (estradiol) patch Estradiol oral tablet MINIVELLE**BNR** (estradiol) patch VIVELLE-DOT**BNR** (estradiol) patch	ALORA (estradiol) patch DOTTI (estradiol) patch ESTRACE (estradiol) oral tablet Estradiol daily patch Estradiol bi-weekly patch	

Table 1: Transdermal Estrogen FDA-Labeled Dosing	
ALORA (estradiol) patch	2/week
CLIMARA (estradiol) patch	1/week
DOTTI (estradiol) patch	2/week
Estradiol patch (once weekly)	1/week
Estradiol patch (twice weekly)	2/week

<table>
<tr>
<td></td>
<td>LYLLANA (estradiol) patch

MENOSTAR (estradiol) patch</td>
<td>
<table>
<tr><td>LYLLANA (estradiol) patch</td><td>2/week</td></tr>
<tr><td>MENOSTAR (estradiol) patch</td><td>1/week</td></tr>
<tr><td>MINIVELLE (estradiol) patch</td><td>2/week</td></tr>
<tr><td>VIVELLE-DOT (estradiol) patch</td><td>2/week</td></tr>
</table>

Note: Estrogen agents are a covered benefit for gender transition/affirming hormone therapy.
</td>
</tr>
<tr><td colspan="3">Therapeutic Drug Class: GLUCAGON, SELF-ADMINISTERED -Effective 10/1/2021</td></tr>
<tr>
<td>No PA Required
(*Must meet eligibility criteria)

GLUCAGEN HYPOKIT (glucagon)

Glucagon Emergency Kit

GVOKE (glucagon)* Hypopen, Syringe</td>
<td>PA Required

BAQSIMI (glucagon) nasal spray

Glucagon Emergency Kit (Fresenius only)

ZEGLAOGUE (dasiglucagon) autoinjector, syringe</td>
<td>*Gvoke (glucagon) may be approved following trial and failure of GlucaGen (glucagon) OR a preferred glucagon emergency kit (failure is defined as allergy to ingredients in product, intolerable side effects, or inability to administer dosage form).

Non-preferred products may be approved if the member has failed treatment with Gvoke (glucagon) AND one other preferred product (failure is defined as allergy to ingredients in product, intolerable side effects, or contraindication to dosing form).

Quantity limit for second-line preferred (Gvoke) and non-preferred products: 2 doses per year unless used / damaged / lost</td>
</tr>
<tr><td colspan="3">Therapeutic Drug Class: GROWTH HORMONES -Effective 4/1/2021</td></tr>
<tr>
<td>No PA Required
(if diagnosis and dose met)

GENOTROPIN cartridge, Miniquick pen

NORDITROPIN Flexpro pen</td>
<td>PA Required

HUMATROPE cartridge, vial

NUTROPIN AQ Nuspin injector

OMNITROPE cartridge, vial

SAIZEN cartridge, vial

SEROSTIM vial

ZOMACTON vial

ZORBTIVE vial</td>
<td>All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1).

Non-preferred Growth Hormone products may be approved if the following criteria are met:

Member failed treatment with one preferred growth hormone product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).
Member has a qualifying diagnosis:

Prader-Willi Syndrome (PWS)
Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30mL/min)
Turner’s Syndrome
Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following:

Has failed at least one GH stimulation test (peak GH level < 10 ng/mL)
Has at least one documented low IGF-1 level (below normal range for patient’s age – refer to range on submitted lab document)

</td>
</tr>
</table>

- Has deficiencies in ≥ 3 pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH)
- Cachexia associated with AIDS
- Noonan Syndrome
- Short bowel syndrome
- Neonatal symptomatic growth hormone deficiency (limited to 3-month PA approval)

- Prescription does not exceed limitations for FDA-labeled maximum dosing for prescribed indication based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*		
Medication	Pediatric Max Dosing (age < 18 years)	Adult Max Dosing (age ≥ 18 years)
Genotropin	0.33 mg/kg/week	0.08 mg/kg/week
Humatrope	0.375 mg/kg/week	0.0875 mg/kg/week
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.357 mg/kg/week	0.175 mg/kg/week for ≤35 years of age 0.0875 mg/kg/week for >35 years of age
Omnitrope	0.33 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for cachexia with HIV only (in combination with antiretroviral therapy)
Zomacton	0.375 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	8 mg/28 days for short bowel syndrome only
*Based on FDA labeled indications and dosing		

VII. Gastrointestinal

Therapeutic Drug Class: **BILE SALTS** -*Effective 4/1/2021*

No PA Required	**PA Required**	**Chenodal** (chenodiol) and **Actigall** (ursodiol) may be approved for members who meet the following criteria: • Member is ≥ 18 years of age AND • Member has tried and failed therapy with a 12-month trial of a preferred ursodiol product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).
Ursodiol capsule	ACTIGALL (ursodiol) capsule	
Ursodiol tablet	CHENODAL (chenodiol) tablet	

	CHOLBAM (cholic acid) capsule OCALIVA (obeticholic acid) tablet URSO (ursodiol) tablet URSO FORTE (ursodiol) tablet	**Cholbam** (cholic acid) may be approved for members who meet the following criteria: • Bile acid synthesis disorders: o Member age must be greater than 3 weeks old AND o Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz). • Peroxisomal disorder including Zellweger spectrum disorders: o Member age must be greater than 3 weeks old AND o Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND o Member has manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. **Ocaliva** (obeticholic acid), **Urso** (ursodiol), and **Urso Forte** (ursodiol) may be approved for members meeting the following criteria: • Member is ≥ 18 years of age AND • Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND • Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis: o Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal o Presence of antimitochondrial antibody with titer of 1:40 or higher o Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND • Member has failed treatment with a preferred ursodiol product for at least 1 year with an inadequate response OR • Member has intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

Therapeutic Drug Class: **ANTI-EMETICS, Oral** -*Effective 1/1/2022*		
No PA Required	**PA Required**	**Ondansetron solution** may be approved for members < 5 years and those members ≥ 5 years of age with a feeding tube.
DICLEGIS DR[BNR] tablet (doxylamine/pyridoxine) Meclizine (Rx) tablet Metoclopramide solution, tablet Ondansetron ODT, tablet	AKYNZEO (netupitant/palonosetron) capsule ANTIVERT (meclizine) tablet Aprepitant capsule, tripack BONJESTA ER (doxylamine/pyridoxine) tablet Doxylamine 25mg (OTC) tablet	**Emend (aprepitant) TriPack** or **Emend (aprepitant) powder kit** may be approved following trial and failure of two preferred products AND Emend (aprepitant) capsule. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Doxylamine/pyridoxine tablet (generic)** or **Bonjesta (doxylamine/pyridoxine)** may be approved for 9 months if meeting the following criteria: • Member has nausea and vomiting associated with pregnancy **AND**

Ondansetron oral suspension/ solution* (<5 years) Prochlorperazine tablet Promethazine syrup, tablet Trimethobenzamide capsule	Doxylamine/pyridoxine tablet (generic Diclegis) Dronabinol capsule EMEND (aprepitant) capsule, powder for suspension, dose/tri pack Granisetron tablet MARINOL (dronabinol) capsule Metoclopramide ODT Pyridoxine 50mg or 100mg (OTC) tablet REGLAN (metoclopramide) tablet TIGAN (trimethobenzamide) capsule VARUBI (rolapitant) tablet ZOFRAN (ondansetron) tablet ZUPLENZ (ondansetron) film	• Member has trialed and failed DICLEGIS DR tablet **AND** one of the following (failure is defined as lack of efficacy with a 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction): o Antihistamine (such as diphenhydramine, dimenhydrinate, meclizine) **OR** o Dopamine antagonist (such as metoclopramide, prochlorperazine, promethazine) **OR** o Serotonin antagonist (ondansetron, granisetron) All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Dronabinol** prior authorization may be approved for members meeting above non-preferred criteria OR via AutoPA for members with documented HIV diagnosis.
Therapeutic Drug Class: **ANTI-EMETICS, Non-Oral** -*Effective 1/1/2022*		
No PA Required Prochlorperazine suppository Promethazine 12.5 mg, 25 mg suppository Scopolamine patch	**PA Required** COMPRO (prochlorperazine) suppository PROMETHEGAN 50 mg (Promethazine) suppository SANCUSO (granisetron) patch TRANSDERM-SCOP patch (scopolamine)	Non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Therapeutic Drug Class: **GI MOTILITY, CHRONIC** -*Effective 10/1/2021*		
PA Required for all agents in this class		All agents will only be approved for FDA labeled indications and up to FDA approved maximum doses listed below. Preferred agents may be approved if the member meets the following criteria: • Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain **AND**
AMITIZA**BNR** (lubiprostone) capsule LINZESS (linaclotide) capsule	Alosetron tablet LOTRONEX (alosetron) tablet Lubiprostone capsule	

MOVANTIK (naloxegol) tablet	MOTEGRITY (prucalopride) tablet RELISTOR (methylnaltrexone) tablet, syringe SYMPROIC (naldemedine) tablet TRULANCE (plecanatide) tablet VIBERZI (eluxadoline) tablet	• Member does not have a diagnosis of GI obstruction **AND** • For indication of OIC, member opioid use must exceed 4 weeks of treatment • For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisocodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisocodyl enema). Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND** • For indication of IBS-D, must have documentation of adequate trial and failure with loperamide and trial and failure with dicyclomine or hyoscyamine. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. Non-preferred agents may be approved if the member meets the following criteria: • Member meets all listed criteria for preferred agents **AND** • Member has trialed and failed two preferred agents OR if the indication is OIC caused by methadone, then a non-preferred agent may be approved after an adequate trial of MOVANTIK (naloxegol). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND** • If prescribed Viberzi (eluxadoline) or Lotronex (alosetron), member meets the additional criteria for those agents listed below. **VIBERZI (eluxadoline)** may be approved for members who meet the following additional criteria: • Diagnosis of Irritable Bowel Syndrome – Diarrhea (IBS-D) **AND** • Member has a gallbladder **AND** • Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas **AND** • Member does not drink more than 3 alcoholic drinks per day **LOTRONEX (alosetron)** and generic alosetron may be approved for members who meet the following additional criteria: • Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer **AND** • Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis, or known mechanical gastrointestinal

		obstruction.

Medication	FDA approved indication	FDA Max Dose
Amitiza (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48mcg/day
Linzess (linaclotide)	IBS-C, CIC	290mcg/day
Movantik (naloxegol)	OIC	25mg/day
Viberzi (eluxadoline)	IBS-D	200mg/day
Relistor syringe (methylnaltrexone)	OIC	12mg SQ/day
Relistor oral (methylnaltrexone)	OIC	450mg/day
Lotronex (alosetron)	IBS-D (females only)	2mg/day (females only)
Symproic (Naldemedine)	OIC	0.2mg/day
Trulance (plecanatide)	CIC, IBS-C	3mg/day
Motegrity (prucalopride)	CIC	2mg/day

CIC – chronic idiopathic constipation, OIC – opioid induced constipation, IBS – irritable bowel syndrome, D – diarrhea predominant, C – constipation predominant

Therapeutic Drug Class: **H. PYLORI TREATMENTS** -*Effective 1/1/2022*

No PA Required	PA Required	
PYLERA tablet (bismuth subcitrate/metronidazole tetracycline)	Amoxicillin/ lansoprazole/clarithromycin OMECLAMOX-PAK (amoxicillin/ omeprazole/clarithromycin) TALICIA tablet (omeprazole/amoxicillin/ rifabutin)	Non-preferred *H. pylori* treatments should be used as individual product ingredients unless one of the individual products is not commercially available, then a PA for the combination product may be given.

Therapeutic Drug Class: **HEMORRHOIDAL, ANORECTAL, AND RELATED TOPICAL ANESTHETIC AGENTS -** *Effective 4/1/2021*

Hydrocortisone single agent

No PA Required	PA Required	
CORTIFOAM (hydrocortisone) 10% aerosol Hydrocortisone 1% cream with applicator Hydrocortisone 2.5% cream with applicator Hydrocortisone enema	COLOCORT (hydrocortisone) enema CORTENEMA (hydrocortisone) enema MICORT-HC (hydrocortisone) cream	Non-preferred products may be approved following trial and failure of therapy with 3 preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

PROCTO-MED HC (hydrocortisone) 2.5% cream PROCTO-PAK (hydrocortisone) 1% cream PROCTOSOL-HC 2.5% (hydrocortisone) cream PROCTOZONE-HC 2.5% (hydrocortisone) cream		
Lidocaine single agent		
No PA Required Lidocaine 5% ointment	**PA Required** Lidocaine 3% cream	
Other and Combinations		
No PA Required Lidocaine-Hydrocortisone 3-0.5% cream with applicator Lidocaine-Prilocaine Cream PROCTOFOAM (hydrocortisone-pramoxine)	**PA Required** Hydrocortisone-Pramoxine 1%-1% cream Hydrocortisone-Pramoxine 2.5%-1% cream Lidocaine-Hydrocortisone in Coleus 2%-2% cream kit Lidocaine-Hydrocortisone 2.8%-0.55% gel Lidocaine-Hydrocortisone 3%-0.5% cream w/o applicator, cream kit Lidocaine-Hydrocortisone 3%-1% cream kit Lidocaine-Hydrocortisone 3%-2.5% gel, gel kit Lidocaine-Prilocaine Kit PLIAGIS (lidocaine-tetracaine) 7%-7% cream RECTIV (nitroglycerin) 0.4% ointment SYNERA (lidocaine-tetracaine) patch	
Therapeutic Drug Class: **PANCREATIC ENZYMES -***Effective 1/1/2022*		
No PA Required	**PA Required**	

CREON (pancrelipase) capsule PANCREAZE (pancrelipase) capsule ZENPEP (pancrelipase) capsule	PERTZYE (pancrelipase) capsule VIOKACE (pancrelipase) tablet	Non-preferred products may be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.) Members currently stabilized on a Non-preferred pancreatic enzyme may receive approval to continue on that agent for one year if medically necessary.
Therapeutic Drug Class: **PROTON PUMP INHIBITORS** -*Effective 1/1/2022*		
No PA Required Esomeprazole DR capsule (RX) Lansoprazole DR capsules (RX) NEXIUM [BNR] (esomeprazole) oral suspension packet Omeprazole DR capsule (RX) Pantoprazole tablet Lansoprazole ODT (lansoprazole) (*for members under 2 years*)	**PA Required** ACIPHEX (rabeprazole) tablet, sprinkle capsule DEXILANT (dexlansoprazole) capsule Esomeprazole DR 49.3 capsule (RX), (OTC) capsule, packet for oral suspension Lansoprazole DR capsule OTC NEXIUM (esomeprazole) capsule (RX), 24HR (OTC) Omeprazole/Na Bicarbonate capsule, packet for oral suspension Omeprazole DR tablet (OTC), ODT (OTC) Pantoprazole packet for oral suspension PREVACID (lansoprazole) capsule, Solutab, suspension PRILOSEC (omeprazole) suspension PROTONIX (pantoprazole DR) tablet, packet for oral suspension Rabeprazole tablet ZEGERID (omeprazole/Na bicarbonate) capsule, packet for oral suspension	For members treating GERD symptoms that are controlled on PPI therapy, it is recommended that the dose of the PPI be re-evaluated or step-down with an H2 blocker (such as famotidine or ranitidine) be trialed in order to reduce long-term PPI use. Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met: ● Member has a qualifying diagnosis (below) **AND** ● Member has trailed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member has been diagnosed using one of the following diagnostic methods: o Diagnosis made by GI specialist o Endoscopy o X-ray o Biopsy o Blood test o Breath Test **Qualifying Diagnoses:** Barrett's esophagus, duodenal ulcer, erosive esophagitis, gastric ulcer, GERD, GI Bleed, H. pylori infection, hypersecretory conditions (Zollinger-Ellison), NSAID-induced ulcer, pediatric esophagitis, requiring mechanical ventilation, requiring a feeding tube **Quantity Limits:** All agents will be limited to once daily dosing except when used for the following diagnoses: Barrett's esophagus, GI Bleed, H. pylori, hypersecretory conditions (Zollinger-Ellison), or members who have spinal cord injury with associated acid reflux. **Adult members with GERD** on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.

		Pediatric members (< 18 years of age) on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy. **Age Limits:** **Nexium 24H** and **Zegerid** will not be approved for members less than 18 years of age. **Prevacid Solutab** may be approved for members < 2 years of age OR for members ≥ 2 years of age with a feeding tube.
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Oral** -*Effective 1/1/2022*		
No PA Required APRISO [BNR] (mesalamine ER) capsule LIALDA [BNR] (mesalamine DR) tablet PENTASA (mesalamine) capsule Sulfasalazine IR and DR tablet	**PA Required** ASACOL HD (mesalamine DR) tablet AZULFIDINE (sulfasalazine) Entab, tablet Balsalazide capsule Budesonide DR tablet COLAZAL (balsalazide) capsule DELZICOL (mesalamine DR) capsule DIPENTUM (olsalazine) capsule Mesalamine DR tablet (generic Asacol HD, Lialda) Mesalamine DR/ER capsule (generic Apriso, Delzicol) UCERIS (budesonide) tablet	Prior authorization for non-preferred oral formulations will require trial and failure of two preferred oral products with different active ingredients AND one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Uceris (budesonide) tablet**: Prior authorization may be approved following trial and failure of one preferred oral product AND one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Approval will be placed for 8 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Rectal** -*Effective 1/1/2022*		
No PA Required Mesalamine suppository Mesalamine 4gm/60 ml enema (generic SF ROWASA)	**PA Required** CANASA (mesalamine) suppository Mesalamine enema, kit ROWASA/SF ROWASA enema, kit (mesalamine) UCERIS (budesonide) foam	Prior authorization for non-preferred rectal formulations will require trial and failure of one preferred rectal formulation and one preferred oral formulation (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). **Uceris (budesonide) foam**: If the above criteria are met, Uceris (budesonide) foam prior authorization may be approved for 6 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

VIII. Hematological

Therapeutic Drug Class: **ANTICOAGULANTS- Oral** -*Effective 10/1/2021*

No PA Required	**PA Required**	
ELIQUIS (apixaban) tablet PRADAXA (dabigatran) capsule Warfarin tablet XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet, dose pack	BEVYXXA (betrixaban) tablet SAVAYSA (edoxaban) tablet XARELTO (rivaroxaban) 2.5 mg tablet	**BEVYXXA** (betrixaban) may be approved if all the following criteria have been met: ● The member has trialed and failed therapy with two preferred agents. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member is not on dialysis **AND** ● The member is need of prophylaxis for DVT following hospitalization for an acute medical illness who are at risk for thromboembolic events due to limited mobility **AND** ● The member does not have a mechanical prosthetic heart valve **SAVAYSA** (edoxaban) may be approved if all the following criteria have been met: ● The member has failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member is not on dialysis **AND** ● Member does not have CrCl > 95 mL/min **AND** ● The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR** ● The member has a diagnosis of non-valvular atrial fibrillation **AND** ● The member does not have a mechanical prosthetic heart valve **XARELTO 2.5mg** (rivaroxaban) may be approved for members meeting all of the following criteria: ● Xarelto 2.5mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND** ● Xarelto 2.5mg is being taken twice daily and in combination with aspirin 75-100mg daily **AND** ● Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND** ● Member must not have had an ischemic, non-lacunar stroke within the past month **AND** ● Member must not have had a hemorrhagic or lacunar stroke at any time All other non-preferred oral agents require trial and failure of two preferred oral agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Continuation of Care: Members with current prior authorization approval on file for a non-preferred <u>oral</u> anticoagulant medication may continue to receive approval for that medication

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTICOAGULANTS- Parenteral -Effective 10/1/2021</td></tr>
<tr><td>No PA Required

Enoxaparin syringe

Enoxaparin vial</td><td>PA Required

ARIXTRA (fondaparinux) syringe

Fondaparinux (generic Arixtra)

FRAGMIN (dalteparin) vial, syringe

LOVENOX (enoxaparin) syringe, vial</td><td>Non-preferred parenteral anticoagulants may be approved if member has trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction

ARIXTRA (fondaparinux) may be approved if the following criteria have been met:
● Member is 18 years of age or older AND
● Member has a CrCl > 30 ml/min AND
● Member weighs > 50 kg AND
● Member has a documented history of heparin induced-thrombocytopenia OR
● Member has a contraindication to enoxaparin

Members currently stabilized on fondaparinux (Arixtra) or dalteparin (Fragmin) may receive prior authorization approval to continue receiving that medication.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTI-PLATELETS -Effective 10/1/2021</td></tr>
<tr><td>No PA Required

AGGRENOX (ASA/dipyridamole) capsule

ASA/dipyridamole ER capsule

BRILINTA (tigacrelor) tablet

Cilostazol tablet

Clopidogrel tablet

Dipyridamole tablet

Pentoxifylline ER tablet

Prasugrel tablet</td><td>PA Required

EFFIENT (prasugrel) tablet

PLAVIX (clopidogrel) tablet

ZONTIVITY (vorapaxar) tablet</td><td>Patients taking Brilinta (ticagrelor) must also be taking a maintenance dose of aspirin not exceeding 100 mg/day.

Zontivity (vorapaxar) may be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case-by-case basis.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: COLONY STIMULATING FACTORS -Effective 10/1/2021</td></tr>
<tr><td colspan="2">PA Required for all agents in this class*</td><td rowspan="2">*Prior authorization for preferred agents may be approved if meeting the following criteria:
• Medication is being used for one of the following indications:
o Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is</td></tr>
<tr><td>NEUPOGEN (filgrastim) vial, syringe

UDENYCA (pegfilgrastim-cbqv)</td><td>FULPHILA (pegfilgrastim-jmdb)

GRANIX (tbo-filgrastim)

LEUKINE (sargramostim)</td></tr>
</table>

ZIEXTENZO (pegfilgrastim-bmez)	NEULASTA (pegfilgrastim) syringe NIVESYM (filgrastim-aafi) ZARXIO (filgrastim-sndz)	less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%) o Acute Myeloid Leukemia (AML) patients receiving chemotherapy o Bone Marrow Transplant (BMT) o Peripheral Blood Progenitor Cell Collection and Therapy o Hematopoietic Syndrome of Acute Radiation Syndrome o Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3) **AND** • For Udenyca (pegfilgrastim-cbqv) or Ziextenzo (pegfilgrastim-bmez), the member meets the following criteria: o Member has trial and failure of Neupogen. Failure is defined as lack of efficacy, intolerable side effects, drug-drug interaction, or contraindication to Neupogen therapy. Trial and failure of Neupogen will not be required if meeting one of the following: ▪ Member has limited access to caregiver or support system for assistance with medication administration **OR** ▪ Member has inadequate access to healthcare facility or home care interventions. Prior authorization for non-preferred agents may be approved if meeting the following criteria: • Medication is being used for one of the following indications: o Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%) o Acute Myeloid Leukemia (AML) patients receiving chemotherapy o Bone Marrow Transplant (BMT) o Peripheral Blood Progenitor Cell Collection and Therapy o Hematopoietic Syndrome of Acute Radiation Syndrome o Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3) **AND** • Member has history of trial and failure of Neupogen AND one other preferred agent. Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, significant drug-drug interactions, or contraindication to therapy. Trial and failure of Neupogen will not be required if meeting one of the following: ▪ Member has limited access to caregiver or support system for assistance with medication administration **OR** ▪ Member has inadequate access to healthcare facility or home care interventions.

Therapeutic Drug Class: **ERYTHROPOIESIS STIMULATING AGENTS** *Effective 10/1/2021*		
PA Required for all agents in this class*		*Prior Authorization is required for all products and may be approved if meeting the following: ● Medication is being administered in the member's home or in a long-term care facility **AND** ● Member meets <u>one</u> of the following: o A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR** o A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR** o A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic) **OR** o A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500 (mU/mL) or less **OR** o Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively **AND** ● For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. †Hemoglobin results must be from the last 30 days.
RETACRIT (epoetin alfa-epbx) (*Pfizer only)*	ARANESP (darbepoetin alfa) EPOGEN (epoetin alfa) MIRCERA (methoxy peg-epoetin beta) PROCRIT (epoetin alfa)	

IX. Immunological

Therapeutic Drug Class: **IMMUNE GLOBULINS** -*Effective 1/1/2022*		
PA Required for all agents in this class*		Preferred agents may be approved for members meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1). Non-preferred agents may be approved for members meeting the following: • Member meets at least one of the approved conditions listed below AND • Member has history of trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) AND • Prescribed dose does not exceed listed maximum (Table 1) Approved Conditions for Immune Globulin Use: • Primary Humoral Immunodeficiency disorders including: o Common Variable Immunodeficiency (CVID)
CUVITRU 20% SQ liquid	BIVIGAM 10% IV liquid	
GAMMAGARD 10% IV/SQ liquid	CUTAQUIG 16.5% SQ liquid	
GAMMAKED 10% IV/SQ liquid	FLEBOGAMMA DIF 5%, 10% IV liquid	
GAMMAPLEX 5%, 10% IV liquid	GAMMAGARD S/D vial	
GAMUNEX-C 10% IV/SQ liquid	HYQVIA 10% SQ liquid	
	OCTAGAM 5%, 10% IV liquid	

HIZENTRA 20% SQ liquid

PRIVIGEN 10% IV liquid

If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.

PANZYGA 10% IV liquid

XEMBIFY 20% IV liquid

- Severe Combined Immunodeficiency (SCID)
- X-Linked Agammaglobulinemia
- X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
- Wiskott-Aldrich Syndrome
- Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm3

- Neurological disorders including:
  - Guillain-Barré Syndrome
  - Relapsing-Remitting Multiple Sclerosis
  - Chronic Inflammatory Demyelinating Polyneuropathy
  - Myasthenia Gravis
  - Polymyositis and Dermatomyositis
  - Multifocal Motor Neuropathy
- Kawasaki Syndrome
- Chronic Lymphocytic Leukemia (CLL)
- Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections
- Autoimmune Hemolytic Anemia (AHA)
- Liver or Intestinal Transplant
- Immune Thrombocytopenia Purpura (ITP) including:
  - Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000
  - Members with active bleeding & platelet count <30,000
  - Pregnant members with platelet counts <10,000 in the third trimester
  - Pregnant members with platelet count 10,000 to 30,000 who are bleeding
- Multisystem Inflammatory Syndrome in Children (MIS-C)

Table 1: FDA-Approved Maximum Immune Globulin Dosing	
Asceniv – IV admin	800 mg/kg every 3 to 4 weeks
Bivigam – IV admin	800 mg/kg every 3 to 4 weeks
Cuvitru – SQ admin	12.6 grams every 2 weeks
Flebogamma DIF – IV admin	600 mg/kg every 3 weeks
Gammaplex 5% -– IV Infusion	800mg/kg every 3 weeks
Gammagard liquid – SQ or IV admin	2.4 grams/kg/month
Gammaked – SQ or IV admin	600 mg/kg every 3 weeks
Gamunex-C – SQ or IV admin	600 mg/kg every 3 weeks
Hizentra – SQ admin	0.4g/kg per week
Octagam – IV admin	600 mg/kg every 3 to 4 weeks
Panzyga – IV admin	2 g/kg every 3 weeks
Privigen – IV admin	2 g/kg

Members currently receiving a preferred or non-preferred immunoglobulin product may receive approval to continue therapy with that product at prescribed doses not exceeding maximum (Table 1).

Therapeutic Drug Class: **NEWER GENERATION ANTIHISTAMINES -***Effective 1/1/2022*		
No PA Required Cetirizine (OTC) tablet, syrup/solution (OTC/RX) Desloratadine tablet (RX) Levocetirizine tablet (RX/OTC) Loratadine tablet (OTC), syrup/solution (OTC)	**PA Required** Cetirizine (OTC) chewable tablet, softgel CLARINEX (desloratadine) tablet Desloratadine ODT (RX) Fexofenadine tablet (OTC), suspension (OTC) Levocetirizine solution (RX) Loratadine chewable (OTC), ODT (OTC)	Non-preferred single agent antihistamine products may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy with a 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Therapeutic Drug Class: **ANTIHISTAMINE/DECONGESTANT COMBINATIONS -** *Effective 1/1/2022*		
No PA Required Loratadine-D (OTC) tablet	**PA Required** Cetirizine-PSE (OTC) CLARINEX-D (desloratadine-D) Fexofenadine/PSE (OTC)	Non-preferred antihistamine/decongestant combinations may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Therapeutic Drug Class: **INTRANASAL RHINITIS AGENTS -***Effective 1/1/2022*		
No PA Required Azelastine 0.15%**,** 137 mcg Budesonide (OTC) Fluticasone (RX) Ipratropium Triamcinolone acetonide (OTC)	**PA Required** Azelastine/Fluticasone BECONASE AQ (beclomethasone dipropionate) DYMISTA (azelastine/ fluticasone) Flunisolide 0.025% Fluticasone (OTC) Mometasone NASONEX (mometasone)	Non-preferred products may be approved following trial and failure of treatment with three preferred products (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred combination agents may be approved following trial of individual products with same active ingredients AND trial and failure of one additional preferred agent (failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions).

	Olopatadine OMNARIS (ciclesonide) PATANASE (olopatadine) QNASL (beclomethasone) XHANCE (fluticasone) ZETONNA (ciclesonide)	
Therapeutic Drug Class: **LEUKOTRIENE MODIFIERS -***Effective 1/1/2022*		
No PA Required Montelukast tablet, chewable	**PA Required** ACCOLATE (zafirlukast) tablet Montelukast granules SINGULAIR (montelukast) tablet, chewable, granules Zafirlukast tablet Zileuton ER tablet ZYFLO (zileuton) tablet	Non-preferred products may be approved if meeting the following criteria: • Member has trialed and failed treatment with one preferred product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND • Member has a diagnosis of asthma. **Montelukast granules** may be approved if a member has tried and failed montelukast chewable tablets AND has difficulty swallowing.
Therapeutic Drug Class: **METHOTREXATE PRODUCTS -***Effective 1/1/2022*		
No PA Required Methotrexate oral tablet, vial	**PA Required** OTREXUP (methotrexate) auto-injector RASUVO (methotrexate) auto-injector REDITREX (methotrexate) syringe TREXALL (methotrexate) oral tablet XATMEP (methotrexate) oral solution	**OTREXUP, REDITREX** or **RASUVO** may be approved if meeting the following criteria: • Member has diagnosis of severe, active rheumatoid arthritis OR active polyarticular juvenile idiopathic arthritis (pJIA) OR inflammatory bowel disease (IBD) **AND** • Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, or inability to take oral product formulation) **AND** • Member is unable to administer preferred methotrexate vial formulation due to limited functional ability (such as vision impairment, limited manual dexterity and/or limited hand strength). **TREXALL** may be approved if meeting the following criteria: • Member has trialed and failed preferred methotrexate tablet formulation. Failure is defined as allergy or intolerable side effects.

		XATMEP may be approved for members who meet the following criteria: • Member is < 18 years of age • Member has a diagnosis of acute lymphoblastic leukemia **OR** • Member has a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) and has had an insufficient therapeutic response to, or is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs) **AND** • Member has a documented swallowing difficulty due to young age and/or a medical condition and is unable to use the preferred methotrexate tablet formulation *Methotrexate can cause serious embryo-fetal harm when administered during pregnancy and it is contraindicated for use during pregnancy for the treatment of non-malignant diseases. Advise members of reproductive potential to use effective contraception during and after treatment with methotrexate, according to FDA product labeling*. Members currently stabilized on a non-preferred methotrexate product may receive approval to continue on that agent.
Therapeutic Drug Class: **MULTIPLE SCLEROSIS AGENTS** -*Effective 4/1/2021*		
Disease Modifying Therapies		
No PA Required (unless indicated*) *Brand/generic changes effective 1/27/2022* AVONEX (interferon beta 1a) injection BETASERON (interferon beta 1b) injection COPAXONE[BNR] (glatiramer) 20MG injection *AUBAGIO (teriflunomide) tablet**2nd Line** *Dimethyl fumarate tablet **2nd Line** *GILENYA (fingolimod) 0.5 mg tablet (30-ct bottle)**2nd Line**	**PA Required** BAFIERTAM (monomethyl fumarate DR) capsule COPAXONE (glatiramer) 40MG injection Dimethyl fumarate tablet EXTAVIA (interferon beta 1b) vial GLATOPA (glatiramer) injection Glatiramer 20mg, 40mg injection GILENYA (fingolimod) 0.25 mg, 0.5 mg tablet (7-ct box) KESIMPTA (ofatumumab) pen MAVENCLAD (cladribine) tablet	*Second-line preferred agents (**Gilenya**, **Tecfidera**, **Aubagio)** may be approved if meeting the following: • Member has documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis AND • Documentation is provided by prescribing neurologist (or name of neurologist consulted may be indicated) supporting marked functional decline as demonstrated by MRI or medical record documentation supporting increased burden of disease AND • Prescriber attests to shared decision making with respect to risks versus benefits of medical treatment AND • Additional safety criteria for prescribed agent are met (Table 1). For members NOT meeting above criteria, second-line preferred agents (Gilenya, Tecfidera, Aubagio) may be approved if meeting all of the following: • Member has a diagnosis of a relapsing form of multiple sclerosis confirmed on MRI by presence of new spinal lesions, cerebellar lesions, brain stem lesions, or change in brain atrophy AND • Medication is being prescribed by a neurologist or in consultation with a neurologist AND • Member has trialed and failed treatment with Avonex (interferon beta 1a) OR Betaseron (interferon beta 1b) OR with Copaxone (glatiramer). Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy. AND • On clinical exam, member has signs and symptoms consistent with functional limitations due to multiple sclerosis that have lasted one month or longer AND

	MAYZENT (siponimod) tablet, pack PLEGRIDY (peg-interferon beta 1a) syringe, pen REBIF (interferon beta 1a) syringe TECFIDERA (dimethyl fumarate) tablet VUMERITY (diroximel DR) capsules ZEPOSIA (ozanimod) capsule	• Additional safety criteria for prescribed agent met (Table 1). <u>Non-Preferred Products:</u> Non-preferred products may be approved following trial and failure with three preferred products. **Mayzent** (simponimod), **Mavenclad** (cladribine), **Vumerity** (dioroxemel fumerate), and **Bafiertam** (monomethyl fumarate DR) must meet specific criteria listed for those agents below. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Copaxone (glatiramer) 40mg** may be approved for members who have severe intolerable injection site reactions to <u>brand</u> Copaxone 20mg (such as pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration). **Mayzent (simponimod)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Member <u>does not</u> have diagnosis of macular degeneration AND • Member has no evidence of relapse in the 3 months preceding initiation of therapy AND • Member has previous trial and failure of three preferred agents, one of which must be Gilenya (fingolimod). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. AND • Additional safety criteria for prescribed agent are met (Table 1) AND • Initial authorization will be limited to 3 months. Continuation (12-month authorization) may be approved with provider attestation that member's symptoms are stable or there is documented clinical improvement. **Mavenclad (cladribine)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Member has history of ≥ 1 relapse in the 12 months preceding initiation of therapy AND • Member has previous trial and failure of three other therapies for relapsing forms of multiple sclerosis (failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects, or significant drug-drug interactions) AND • Additional safety criteria for prescribed agent are met (Table 1). **Vumerity (diroximel fumarate)** or **Bafiertam (monomethyl fumarate DR)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Additional safety criteria for prescribed agent are met (Table 1) AND • Member has previous trial and failure of three preferred agents, one of which must be Tecfidera (dimethyl fumarate). Failure is defined as lack of efficacy, allergy,

		intolerable side effects [if GI adverse events, must meet additional criteria below], or significant drug-drug interactions) AND • If Vumerity (diroximel fumarate) or Bafiertam (monomethyl fumarate DR) is being prescribed due to GI adverse events with Tecfidera (dimethyl fumarate) therapy (and no other reason for failure of Tecfidera is given), then the following additional criteria must be met: o Member has trialed a temporary dose reduction of Tecfidera (with maintenance dose being resumed within 4 weeks) AND o Member has trialed taking Tecfidera (dimethyl fumarate) with food AND o GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) AND o Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events with Vumerity (diroximel fumarate) therapy or Bafiertam (monomethyl fumarate DR). Grandfathering: Members currently stabilized on a preferred second-line product or a non-preferred product may receive approval to continue therapy with that agent.

Table 1: Safety Criteria for Initiating Multiple Sclerosis Disease Modifying Therapy

Brand	AUBAGIO	BAFIERTAM	GILENYA	MAYZENT	MAVENCLAD	TECFIDERA	VUMERITY
Generic	teriflunomide	monomethyl fumarate DR	fingolimod	simponimod	cladribine	dimethyl fumarate	diroximel fumarate
No active infections [a]	X	X	X	X	X	X	X
CBC w/lymphocytes	X	X (> 500)	X	X	X (WNL) [c, g]	X (> 500)	X (> 500)
ALT, AST, bilirubin ≤ 2x ULN [b]	X Boxed warning	X	X	X	X	X	X
Negative baseline pregnancy test	X Boxed warning	X	X	X	X Boxed warning	X	
Using highly effective contraception (if childbearing potential)	X	X	X	X	X	X	X
Other	• Documented baseline blood pressure • No severe hepatic impairment • Pre-therapy screening for TB • Member is not taking leflunomide (ARAVA)	• Member is not taking TECFIDERA (dimethyl fumarate) or VUMERITY (diroximel fumarate) • No known allergy to fumarate agents for MS • Member counseled regarding PML[e]	• No significant CV history [f] • QTc interval ≤ 500 ms • No Class 1a or Class III antiarrhythmic use • Baseline eye evaluation that includes macula exam	• No CYP2C9*3/*3 genotype • No significant CV history [f] • QTc interval < 500 ms • Baseline eye evaluation that includes macula exam	• No current evidence of malignancy (Boxed warning) • Screening MRI for PML within 3 months prior to therapy [e] • No current immunosuppressive or myelosuppressive therapy • Screening for TB, HBV and HCV • No breastfeeding	• Member not taking BAFIERTAM (monomethyl fumarate) or VUMERITY (diroximel fumarate) • No known allergy to fumarate agents for MS • Member counseled regarding PML[e]	• Member not taking TECFIDERA (dimethyl fumarate) or BAFIERTAM (monomethyl fumarate) • No known allergy to fumarate agents for MS • Member counseled regarding PML[e]
Maximum dose	14 mg per day	190 mg twice a day	Age and weight based [d]	60 mg per 30 days	Not exceeding 3.5mg/kg during full treatment course	240 mg twice a day	924 mg per day

a – including herpes zoster or other active acute serious infections or chronic infections such as hepatitis, tuberculosis and HIV
b – ULN: upper limit of normal
c – plus at 2 and 6 months post-drug therapy initiation and periodically thereafter
d – GILENYA maximum dose: ≥ 10 years of age and > 40 kg body weight: 0.5 mg once daily, ≥ 10 years of age and ≤ 40 kg body weight: 0.25 mg once daily
e – PML: progressive multifocal leukoencephalopathy
f – No history of MI, CVA, TIA, unstable angina, decompensated HF requiring hospitalization, NYHA Class III-IV HF **AND** no Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
g – Lymphocytes must be within normal limits (WNL) before initiating the first treatment course and ≥ 800 cells per microliter before initiating the second treatment course

Symptom Management Therapies

	PA Required AMPYRA ER (dalfampridine) tablet Dalfampridine ER tablet	**Ampyra** (dalfampridine) prior authorization may be approved if all of the following criteria are met: • Member has a diagnosis of MS; Member is ambulatory and has established a baseline which is defined as ambulating between 8-45 seconds Timed 25-foot Walk (T25FW) assessment OR has established a baseline activities of daily living (ADL) AND • Member has no history of seizure disorder AND

		• Member has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min) AND • Prescriber is a neurologist or is prescribed in consultation with a neurologist AND • The prescribed dose does not exceed 10 mg twice daily. Reauthorization of Ampyra (dalfampridine) may be approved if medical record documentation indicates that member's symptoms are stable or there is improvement in ambulation (measured by T25FW assessment) or improvement in ADLs.
Therapeutic Drug Class: **TARGETED IMMUNE MODULATORS -***Effective 1/1/2022* *Preferred agents:* ENBREL (etanercept); HUMIRA (adalimumab); OTEZLA (apremilast) tablet; KEVZARA (sarilumab); TALTZ (ixekizumab); XELJANZ IR (tofacitinib) tablet		
Rheumatoid Arthritis, Polyarticular Course Juvenile Idiopathic Arthritis, and Ankylosing Spondylitis		
No PA Required **(if diagnosis met)** **(*Must meet eligibility criteria)** ENBREL (etanercept) HUMIRA (adalimumab) *KEVZARA (sarilumab) pen, syringe *TALTZ (ixekizumab) XELJANZ IR (tofacitinib) tablet	**PA Required** ACTEMRA (tocilizumab) syringe, Actpen CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector ILARIS (canakinumab) vial KINERET (anakinra) syringe OLUMIANT (baricitinib) tablet ORENCIA (abatacept) syringe, clickject RINVOQ (upadacitinib) tablet SIMPONI (golimumab) pen, syringe XELJANZ (tofacitinib) solution XELJANZ XR (tofacitinib ER) tablet ***for information on IV infused Targeted Immune Modulators please see Appendix P**	First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply ***TALTZ (ixekizumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL. ***KEVZARA (sarilumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR. **KINERET (anakinra)** may receive approval for: • FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **OR** • Treatment of systemic juvenile idiopathic arthritis (sJIA) or Adult Onset Still's Disease (AOSD) **ILARIS (canakinumab)** may receive approval if meeting the following: • Medication is being prescribed for systemic juvenile idiopathic arthritis (sJIA) or Adult Onset Still's Disease (AOSD), **AND** • Member has trialed and failed‡ KINERET (anakinra) **AND** ACTEMRA (tocilizumab) **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below. All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred agents.

		‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Members currently taking COSENTYX may receive approval to continue on that agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Psoriatic Arthritis		
No PA Required (if diagnosis met) (*Must meet eligibility criteria) ENBREL (etanercept) HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab) XELJANZ IR (tofacitinib) tablet	**PA Required** CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector ORENCIA (abatacept) syringe, clickject RINVOQ (upadacitinib) tablet SIMPONI (golimumab) pen, syringe STELARA (ustekinumab) syringe TREMFYA (guselkumab) injector, syringe XELJANZ XR (tofacitinib ER) tablet ***for information on IV infused Targeted Immune Modulators please see Appendix P**	First line preferred agents (HUMIRA, ENBREL, XELJANZ IR) may receive approval for psoriatic arthritis indication. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply ***OTEZLA (apremilast)** may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or TALTZ. ***TALTZ (ixekizumab)** may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or OTEZLA. **STELARA (ustekinumab) syringe for subcutaneous use may** receive approval if meeting the following: ▪ Member has trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA **AND** ▪ Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND** ▪ Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response. **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below. All other non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR **AND** TALTZ or OTEZLA. ‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

<table>
<tr><td></td><td></td><td>Members currently taking COSENTYX may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.</td></tr>
<tr><td colspan="3">Plaque Psoriasis</td></tr>
<tr><td>No PA Required
(if diagnosis met)
(*Must meet eligibility criteria)

ENBREL (etanercept)

HUMIRA (adalimumab)

*OTEZLA (apremilast) tablet

*TALTZ (ixekizumab)</td><td>PA Required

CIMZIA (certolizumab) kit

COSENTYX (secukinumab) syringe, pen-injector

SILIQ (brodalumab) syringe

SKYRIZI (risankizumab-rzaa) syringe, kit

STELARA (ustekinumab) syringe

TREMFYA (guselkumab) injector, syringe

*for information on IV infused Targeted Immune Modulators please see Appendix P</td><td>First line preferred agents (HUMIRA, ENBREL) may receive approval for plaque psoriasis indication.

*Second line preferred agents (TALTZ, OTEZLA) may receive approval for plaque psoriasis indication following trial and failure‡ of HUMIRA OR ENBREL.

STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:
▪ Member has trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two indicated second line agents (TALTZ, OTEZLA), AND
▪ Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy AND
▪ Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response.

All other non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two second line agents (TALTZ, OTEZLA).

‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Members currently taking COSENTYX may receive approval to continue on that agent.

The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.</td></tr>
<tr><td colspan="3">Crohn's Disease and Ulcerative Colitis</td></tr>
<tr><td>No PA Required
(if diagnosis met)
(*Must meet eligibility criteria)

HUMIRA (adalimumab)</td><td>PA Required

CIMZIA (certolizumab) kit

SIMPONI (golimumab) pen, syringe</td><td>First line preferred agents (HUMIRA) may receive approval for Crohn's disease and ulcerative colitis indications.

*XELJANZ IR may receive approval for ulcerative colitis indication following trial and failure‡ of HUMIRA.</td></tr>
</table>

*XELJANZ IR (tofacitinib) tablet	STELARA (ustekinumab) syringe XELJANZ XR (tofacitinib ER) tablet ***for information on IV infused Targeted Immune Modulators please see Appendix P**	**Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply **STELARA (ustekinumab) syringe for subcutaneous use may** receive approval if meeting the following: ▪ For treatment of moderately-to-severely active Crohn's disease, member has trial and failure† of all indicated preferred agents (HUMIRA) **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure† of all indicated preferred agents (HUMIRA and XELJANZ IR) **AND** ▪ Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND** ▪ Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response. **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below. All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure† of all indicated preferred agents. Members currently taking COSENTYX may receive approval to continue on that agent. †Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Other indications		
Must meet eligibility criteria*	**PA Required**	First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications.
ENBREL (etanercept) HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab)	ACTEMRA (tocilizumab) syringe, Actpen ARCALYST (rilonacept) injection CIMZIA (certolizumab) kit	**Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply *Second-line preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first-line preferred agents (ENBREL, HUMIRA, XELJANZ IR).

XELJANZ IR (tofacitinib) tablet	COSENTYX (secukinumab) syringe, pen-injector ILARIS (canakinumab) vial KINERET (anakinra) syringe ***for information on IV infused Targeted Immune Modulators please see Appendix P**	**ARCALYST (rilonacept)** may receive approval if meeting the following: • Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed below): o Cryopyrin-associated Autoinflammatory Syndrome (CAPS), including: ▪ Familial Cold Autoinflammatory Syndrome (FCAS) ▪ Muckle-Wells Syndrome (MWS) o Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg o Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children ≥ 12 years of age **AND** • Member has trialed and failed‡ colchicine **AND** • Initial approval will be given for 12 weeks and authorization approval for continuation will be provided based on clinical response. **ILARIS (canakinumab)** may receive approval if meeting the following: • Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed below): o Familial Mediterranean Fever (FMF) o Hyperimmunoglobulinemia D syndrome (HIDS) o Mevalonate Kinase Deficiency (MKD) o Neonatal onset multisystem inflammatory disease (NOMID) o TNF Receptor Associated Periodic Syndrome (TRAPS) o Cryopyrin-associated Autoinflammatory Syndrome (including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome) **AND** • Member has trialed and failed‡ colchicine. **KINERET (anakinra)** may receive approval if meeting the following: • Medication is being prescribed for one of the following indications (approval for all other indications is subject to meeting non-preferred criteria below): o Neonatal onset multisystem inflammatory disease (NOMID). o Familial Mediterranean Fever (FMF) **AND** • Member has trialed and failed‡ colchicine. All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred agents (ENBREL, HUMIRA, XELJANZ IR, TALTZ, OTEZLA).

		‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Members currently taking COSENTYX (secukinumab) may receive approval to continue on that agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*

X. Miscellaneous

Therapeutic Drug Class: **EPINEPHRINE PRODUCTS** -*Effective 1/1/2022*		
No PA Required	**PA Required**	Non-preferred products may be approved if the member has failed treatment with one of the preferred products. Failure is defined as allergy to ingredients in product or intolerable side effects. Quantity limit: 4 auto injectors per year unless used / damaged / lost
EPIPEN[BNR] 0.3 mg/0.3 ml (epinephrine) auto-injector EPIPEN JR[BNR] 0.15 mg/0.15 ml, (epinephrine) auto-injector	Epinephrine 0.15mg/0.15ml, 0.3mg/0.3ml auto-injector (generic Adrenaclick, Epipen) SYMJEPI 0.15mg/0.3ml, 0.3mg/0.3ml (epinephrine) syringe	

Therapeutic Drug Class: **NEWER HEREDITARY ANGIOEDEMA PRODUCTS** -*Effective 1/1/2022*		
PA Required for all agents in this class		Medications Indicated for Routine Prophylaxis:
Prophylaxis: HAEGARDA (C1 esterase inhibitor) vial *Treatment:* BERINERT (C1 esterase inhibitor) kit Icatibant syringe (generic FIRAZYR)	*Prophylaxis:* CINRYZE (C1 esterase inhibitor) kit ORLADEYO (berotralstat) oral capsule TAKHZYRO (lanadelumab-flyo) vial *Treatment:* FIRAZYR (icatibant acetate) syringe RUCONEST (C1 esterase inhibitor, recomb) vial	Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year. **HAEGARDA** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member meets at least one of the following: ▪ Haegarda is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR** ▪ Haegarda is being used for long-term prophylaxis and member meets one of the following: o History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR** o History of laryngeal attacks **OR** o History of ≥2 attacks per month involving the face, throat, or abdomen **AND**

		○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV Maximum Dose: 60 IU/kg Minimum Age: 10 years **CINRYZE** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of Haegarda. Failure is defined as lack of efficacy allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member meets at least one of the following: ▪ Cinryze is being used for <u>short-term prophylaxis</u> to undergo a surgical procedure or major dental work **OR** ▪ Cinryze is being used for <u>long-term prophylaxis</u> and member meets one of the following: ○ History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR** ○ History of laryngeal attacks **OR** ○ History of ≥2 attacks per month involving the face, throat, or abdomen **AND** ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV. Minimum age: 6 years Maximum dose: 100 Units/kg **ORLADEYO** (berotralstat) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to

		severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND** o ORLADEYO is prescribed by or in consultation with an allergist or immunologist **AND** o Appropriate drug interaction interventions will be made for members using concomitant medications that may require dose adjustments (such as cyclosporine, fentanyl, pimozide, digoxin) **AND** o Member meets at least one of the following: ▪ ORLADEYO is being used for short-term prophylaxis to undergo a surgical procedure or major dental work ▪ ORLADEYO is being used for long-term prophylaxis and member meets one of the following: • History of ≥ 1 attack per month resulting in documented ED admission or hospitalization **OR** • History of laryngeal attacks **OR** • History of ≥ 2 attacks per month involving the face, throat, or abdomen **AND** • Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications Minimum age:12 years Maximum dose: 150 mg once daily **TAKHZYRO** (lanadelumab-flyo) may be approved for members meeting the following criteria: o Member has history of trial and failure of Haegarda. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND** o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** o Member has received hepatitis A and hepatitis B vaccination. Minimum age: 12 years Maximum dose: The recommended starting dose is 300mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (attack free) for more than 6 months **<u>Medications Indicated for Treatment of Acute Attacks:</u>**

		Members are restricted to coverage of one medication for <u>treatment of acute attacks</u> at one time. Prior authorization approval will be for one year. **FIRAZYR** (icatibant acetate) may be approved for members meeting the following criteria: o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications Minimum age: 18 years Maximum dose: 30mg **BERINERT** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** o Member has received hepatitis A and hepatitis B vaccination **AND** o Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV Minimum age: 6 years Max dose: 20 IU/kg **RUCONEST** (C1 esterase inhibitor (recombinant)) may be approved for members meeting the following criteria: o Member has a history of trial and failure of Firazyr OR Berinert. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling,

		airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** o Member has received hepatitis A and hepatitis B vaccination **AND** o Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV. Minimum age: 13 years Maximum dose: 4200 Units/dose All other non-preferred agents may be approved if the member has trialed and failed at least two preferred agents with the same indicated role in therapy as the prescribed medication (prophylaxis or treatment). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.
Therapeutic Drug Class: **PHOSPHATE BINDERS** -*Effective 7/1/2021*		
No PA Required *Brand/generic changes effective 07/15/21* Calcium acetate capsule PHOSLYRA (calcium acetate) RENAGEL[BNR] (sevelamer HCl 800mg tablet) RENVELA[BNR] (sevelamer carbonate) tablet RENVELA[BNR] (sevelamer carbonate) powder pack Sevelamer HCl 800mg tablet	**PA Required** AURYXIA (ferric citrate) Calcium acetate tablet CALPHRON (calcium acetate) FOSRENOL (lanthanum carbonate) chewable tablet, powder pack Lanthanum carbonate chewable tablet, powder pack Sevelamer carbonate tablet, powder pack Sevelamer HCl 400mg tablet VELPHORO (sucroferric oxide)	Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria: ● Member has diagnosis of end stage renal disease AND ● Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND ● Provider attests to member avoidance of high phosphate containing foods from diet AND ● Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product). **Auryxia** (ferric citrate) may be approved if the member meets all the following criteria: ● Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND ● Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND ● Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease OR ● Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND ● Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX) **Velphoro** (sucroferric oxyhydroxide tablet, chewable) may be approved if the member meets all of the following criteria: • Member is diagnosed with chronic kidney disease and receiving dialysis and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND

		• Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND • Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product Maximum Dose: Velphoro 3000mg daily Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product. ‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction. *Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.*
Therapeutic Drug Class: **PRENATAL VITAMINS / MINERALS** -*Effective 10/1/2021*		
***Must meet eligibility criteria** COMPLETE NATAL DHA tablet M-NATAL PLUS tablet NESTABS tablets PNV 29-1 tablet PREPLUS CA-FE 27 mg – FA 1 mg tablet SE-NATAL 19 chewable tablet THRIVITE RX tablet TRINATAL RX 1 tablet VITAFOL gummies VP-PNV-DHA softgel WESTAB PLUS tablet	**PA Required** All other rebateable prescription products are non-preferred	*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to become pregnant. Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.
XI. Ophthalmic		
Therapeutic Drug Class: **OPHTHALMIC, ALLERGY** -*Effective 4/1/2021*		
No PA Required	**PA Required**	

ALREX (loteprednol) 2% Cromolyn 4% Ketotifen 0.025% (OTC) LASTACAFT (alcaftadine) 0.25% Olopatadine 0.1%, 0.2% (RX) PAZEO (olopatadine) 0.7% (RX)	ALAWAY (ketotifen) 0.025% (OTC) ALOCRIL (nedocromil) 2% ALOMIDE (lodoxamide) 0.1% Azelastine 0.05% BEPREVE (bepotastine) 1.5% Epinastine 0.05% PATADAY (olopatadine) 0.2% (OTC) PATADAY ONCE DAILY (olopatadine) 0.7% (OTC) PATADAY TWICE DAILY (olopatadine) 0.1% (OTC) ZADITOR (ketotifen) 0.025% (OTC) ZERVIATE (cetirizine) 0.24%	Non-preferred products may be approved following trial and failure of therapy with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).
Therapeutic Drug Class: **OPHTHALMIC, IMMUNOMODULATORS** -*Effective 10/1/2021*		
No PA Required RESTASIS (cyclosporine 0.05%) BNR	**PA Required** CEQUA (cyclosporine 0.09%) solution RESTASIS MULTIDOSE (cyclosporine 0.05%) XIIDRA (lifitegrast)	Non-preferred products may be approved for members meeting all of the following criteria: ● Member is 18 years and older **AND** ● Member has a diagnosis of chronic dry eye **AND** ● Member has failed a 3-month trial of one preferred product. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** ● Prescriber is an ophthalmologist, optometrist or rheumatologist <u>Maximum Dose/Quantity:</u> 60 single use containers for 30 days 5.5 mL/20 days for Restasis Multi-Dose
Therapeutic Drug Class: **OPHTHALMIC, ANTI-INFLAMMATORIES** -*Effective 4/1/2021*		
NSAIDs		Non-preferred products may be approved with trial and failure of three preferred agents (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).
No PA Required	**PA Required**	
Diclofenac 0.1%	ACULAR (ketorolac) 0.5%, LS 0.4%	

Flurbiprofen 0.03% ILEVRO (nepafenac) 0.03% Ketorolac 0.5%, Ketorolac LS 0.4%	ACUVAIL (ketorolac/PF) 0.45% Bromfenac 0.09% BROMSITE (bromfenac) 0.075% NEVANAC (nepafenac) 0.1% PROLENSA (bromfenac) 0.07%	**Durezol** (**difluprednate**) may be approved if meeting the following criteria: • Member has a diagnosis of severe intermediate uveitis, severe panuveitis, or severe uveitis with the complication of uveitic macular edema AND has trialed and failed prednisolone acetate 1% (failure is defined as lack of efficacy, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) OR • Members with a diagnosis other than those listed above require trial and failure of three preferred agents (failure is defined as lack of efficacy, allergy, contraindication, intolerable side effects, or significant drug-drug interaction). **Lotemax SM (loteprednol etabonate)** may be approved if meeting all of the following: • Member is ≥18 years of age AND • Lotemax SM (loteprednol etabonate) is being used for the treatment of post-operative inflammation and pain following ocular surgery AND • Member has trialed and failed therapy with two preferred loteprednol formulations (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) AND • Member has trialed and failed therapy with two preferred agents that do not contain loteprednol (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) AND • Member does not have any of the following conditions: o Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella OR o Mycobacterial infection of the eye and fungal diseases of ocular structures
Corticosteroids		
No PA Required	**PA Required**	
FLAREX (fluorometholone) 0.1% Fluorometholone 0.1% drops FML FORTE (fluorometholone) 0.25% drops LOTEMAX (loteprednol) 0.5% drops[BNR], 0.5% ointment MAXIDEX (dexamethasone) 0.1% PRED MILD (prednisolone) 0.12% Prednisolone acetate 1%	Dexamethasone 0.1% DUREZOL (difluprednate) 0.05% EYSUVIS (loteprednol) 0.25% FML LIQUIFILM (fluorometholone) 0.1% drop FML S.O.P (fluorometholone) 0.1% ointment INVELTYS (loteprednol) 1% LOTEMAX (loteprednol) 0.5% gel LOTEMAX SM (loteprednol) 0.38% gel Loteprednol 0.5% drops OMNIPRED (prednisolone) 1% PRED FORTE (prednisolone) 1% Prednisolone sodium phosphate 1%	
Therapeutic Drug Class: **OPHTHALMIC, GLAUCOMA -***Effective 4/1/2021*		
Beta-blockers		Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha2-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.
No PA Required	**PA Required**	
Levobunolol Timolol (generic Timoptic)	Betaxolol	

	BETOPIC-S (betaxolol) Carteolol ISTALOL (timolol) Timolol (generic Istalol) drops Timolol GFS TIMOPTIC, TIMOPTIC OCUDOSE (timolol) TIMOPTIC-XE (timolol GFS)	Non-preferred combination products may be approved following trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the combination product being requested (if available) to establish tolerance. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions. Preservative free products may be approved with provider documentation of adverse effect to preservative-containing product.
Carbonic anhydrase inhibitors		
No PA Required	**PA Required**	
AZOPT (brinzolamide) Dorzolamide	TRUSOPT (dorzolamide)	
Prostaglandin analogue		
No PA Required	**PA Required**	
Latanoprost 0.005% LUMIGAN (bimatoprost) 0.01% TRAVATAN Z[BNR] (travoprost)	Bimatoprost 0.03% Latanoprost PF 0.005% Travoprost 0.004% VYZULTA (latanoprostene) 0.024% XALATAN (latanoprost) 0.005% XELPROS (latanoprost) 0.005% ZIOPTAN (tafluprost PF) 0.0015%	
Alpha-2 adrenergic agonists		
No PA Required	**PA Required**	
ALPHAGAN P 0.1% (brimonidine)	Apraclonidine 0.5% Brimonidine 0.15%	

ALPHAGAN P [BNR] 0.15% (brimonidine) Brimonidine 0.2%	IOPIDINE (apraclonidine) 0.5%, 1%	
Other ophthalmic, glaucoma and combinations		
No PA Required	**PA Required**	
COMBIGAN [BNR] (brimonidine/timolol) Dorzolamide/Timolol Dorzolamide/Timolol PF	COSOPT/COSOPT PF (dorzolamide/timolol) ISOPTO CARPINE (pilocarpine) PHOSPHOLINE IODIDE (echothiophate) Pilocarpine RHOPRESSA (netarsudil) ROCKLATAN (netarsudil/latanoprost) SIMBRINZA (brinzolamide/brimonidine)	

XII. Renal/Genitourinary

Therapeutic Drug Class: **BENIGN PROSTATIC HYPERPLASIA (BPH) AGENTS -***Effective 7/1/2021*		
No PA Required	**PA Required**	
Alfuzosin ER tablet Doxazosin tablet Dutasteride capsule Finasteride tablet Tamsulosin capsule Terazosin capsule	AVODART (dutasteride) CARDURA (doxazosin) CARDURA XL (doxazosin ER) *CIALIS (tadalafil) 2.5 mg, 5 mg Dutasteride/tamsulosin FLOMAX (tamsulosin) JALYN (dutasteride/tamsulosin) PROSCAR (finasteride)	Prior authorization for non-preferred products in this class may be approved if member meets all of the following criteria: ● Member has tried and failed‡ three preferred agents AND ● For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent. ‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. ***CIALIS** (tadalafil) may be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following: ● AUA Prostate Symptom Score ≥ 8 AND ● Results of a digital rectal exam.

	RAPAFLO (silodosin) Silodosin capsule *Tadalafil 2.5 mg, 5 mg	Cialis (tadalafil) will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population. Doses exceeding 5mg per day of Cialis (tadalafil) will not be approved.
Therapeutic Drug Class: **ANTI-HYPERURICEMICS -***Effective 1/1/2022*		
No PA Required *Brand/generic changes effective 1/27/2022* Allopurinol tablet Colchicine tablet Probenecid tablet Probenecid/Colchicine tablet	**PA Required** Colchicine capsule COLCRYS (colchicine) tablet Febuxostat tablet GLOPERBA (colchicine) oral solution MITIGARE (colchicine) capsule ULORIC (febuxostat) tablet ZYLOPRIM (allopurinol) tablet	Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol. Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **GLOPERBA (colchicine)** oral solution may be approved for members who require individual doses <0.6 mg OR for members who have documented swallowing difficulty due to young age and/or a medical condition (preventing use of solid oral dosage form). Colchicine tablet quantity limits: • Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days • Familial Mediterranean Fever: 120 tablets per 30 days
Therapeutic Drug Class: **OVERACTIVE BLADDER AGENTS -***Effective 10/1/2021*		
No PA Required GELNIQUE (oxybutynin) gel MYRBETRIQ (mirabegron) tablet Oxybutynin IR, ER tablets, syrup Oxybutynin ER tablets Solifenacin tablet TOVIAZ (fesoterodine ER)	**PA Required** Darifenacin ER tablet DETROL (tolterodine) DETROL LA (tolterodine ER) DITROPAN (brand) DITROPAN XL (brand) ENABLEX (darifenacin) Flavoxate GELNIQUE (oxybutynin) gel pump MYRBETRIQ (mirabegron) suspension	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Members with hepatic failure can receive approval for trospium (Sanctura) or trospium extended release (Sanctura XR) products without a trial on a Preferred product.

	OXYTROL (oxybutynin patch) SANCTURA (trospium) SANCTURA XL (trospium ER) Tolterodine Trospium ER capsule, tablet VESICARE (solifenacin)	

XIII. RESPIRATORY

Therapeutic Drug Class: **RESPIRATORY AGENTS** -*Effective 1/1/2022*

Inhaled Anticholinergics

No PA Required (unless indicated*)	**PA Required**	
Solutions Ipratropium solution **Short-Acting Inhalation Devices** ATROVENT HFA (ipratropium) **Long-Acting Inhalation Devices** SPIRIVA Handihaler (tiotropium) *SPIRIVA RESPIMAT (tiotropium)	**Solutions** LONHALA MAGNAIR (glycopyrrolate) solution YUPELRI (revefenacin) solution **Short-Acting Inhalation Devices** **Long-Acting Inhalation Devices** INCRUSE ELLIPTA (umeclidinium) SEEBRI NEOHALER (glycopyrrolate) TUDORZA PRESSAIR (aclidinium)	***SPIRIVA RESPIMAT (tiotropium) 1.25 mcg** may be approved for members ≥ 6 years of age with a diagnosis of asthma (qualifying diagnosis verified by AutoPA). SPIRIVA RESPIMAT is intended to be used by members whose asthma is not controlled with regular use of a combination medium-dose inhaled corticosteroid and long-acting beta agonist (LABA). ***SPIRIVA RESPIMAT (tiotropium)** 2.5 mcg may be approved for members with a diagnosis of COPD who have trialed and failed SPIRIVA HANDIHALER. Failure is defined as intolerable side effects or inability to use dry powder inhaler (DPI) formulation. **LONHALA MAGNAIR** (glycopyrrolate) may be approved for members ≥ 18 years of age with a diagnosis of COPD including chronic bronchitis and emphysema who have trialed and failed‡ treatment with two preferred anticholinergic agents. Non-preferred single agent anticholinergic agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred agents, one of which must be SPIRIVA HANDIHALER. ‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Inhaled Anticholinergic Combinations

No PA Required	**PA Required**	
Solutions Albuterol/ipratropium solution	**Solutions**	

Short-Acting Inhalation Devices COMBIVENT RESPIMAT (albuterol/ipratropium) **Long-Acting Inhalation Devices** ANORO ELLIPTA (umeclidinium/vilanterol)	**Short-Acting Inhalation Devices** **Long-Acting Inhalation Devices** BEVESPI AEROSPHERE (glycopyrrolate /formoterol fumarate) BREZTRI AEROSPHERE (budesonide/glycopyrrolate/ formoterol) DUAKLIR PRESSAIR (aclidinium/formoterol) STIOLTO RESPIMAT (tiotropium/olodaterol) UTIBRON NEOHALER (glycopyrrolate/indacaterol)	**BREZTRI AEROSPHERE** (budesonide/glycopyrrolate/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents. **DUAKLIR PRESSAIR** (aclidinium/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents. All other non-preferred inhaled anticholinergic combination agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred inhaled anticholinergic combination agents OR three preferred inhaled anticholinergic-containing agents (single ingredient or combination). Members who are currently stabilized on Bevespi Aerosphere may receive approval to continue therapy with that product. ‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.
Inhaled Beta2 Agonists (short acting)		
No PA Required **Solutions** Albuterol solution, for nebulizer **Inhalers** PROAIR [BNR] HFA (albuterol) VENTOLIN [BNR] HFA (albuterol)	**PA Required** **Solutions** Levalbuterol solution XOPENEX (levalbuterol) solution **Inhalers** Albuterol HFA Levalbuterol HFA PROAIR DIGIHALER, RESPICLICK (albuterol) PROVENTIL (albuterol) HFA inhaler XOPENEX (levalbuterol) Inhaler	Non-preferred, short acting beta2 agonists may be approved for members who have failed treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. MDI formulation quantity limits: 2 inhalers / 30 days
Inhaled Beta2 Agonists (long acting)		
***Must meet eligibility criteria** **Solutions**	**PA Required** **Solutions** BROVANA (arformoterol) solution PERFOROMIST (formoterol) solution	***SEREVENT** (salmeterol) may be approved for members with moderate to very severe COPD. Serevent will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.

Inhalers *SEREVENT DISKUS (salmeterol) inhaler	**Inhalers** STRIVERDI RESPIMAT (olodaterol)	Non-preferred agents may be approved for members with moderate to severe COPD, AND members must have failed a trial of Serevent. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid therapeutic class.
Inhaled Corticosteroids		
No PA Required **Solutions** Budesonide nebules **Inhalers** ASMANEX Twisthaler (mometasone) FLOVENT DISKUS (fluticasone) FLOVENT HFA (fluticasone) PULMICORT FLEXHALER (budesonide)	**PA Required** **Solutions** PULMICORT (budesonide) nebules **Inhalers** ALVESCO (ciclesonide) inhaler ARMONAIR DIGIHALER (fluticasone propionate) ARNUITY ELLIPTA (fluticasone furoate) ASMANEX HFA (mometasone furoate) inhaler QVAR REDIHALER (beclomethasone)	Non-preferred inhaled corticosteroids may be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.) Maximum Dose: Pulmicort (budesonide) nebulizer suspension: 2mg/day
Inhaled Corticosteroid Combinations		
No PA Required ADVAIR DISKUS[BNR] (fluticasone/salmeterol) ADVAIR HFA (fluticasone/salmeterol) DULERA (mometasone/ formoterol) SYMBICORT[BNR] (budesonide/formoterol) inhaler	**PA Required** AIRDUO DIGIHALER, RESPICLICK (fluticasone/salmeterol) BREO Ellipta (vilanterol/fluticasone furoate) Budesonide/formoterol (generic Symbicort) Fluticasone/salmeterol (generic Airduo) Fluticasone/salmeterol (generic Advair) TRELEGY ELLIPTA (fluticasone furoate/ umeclidinium/vilanterol) WIXELA INHUB (fluticasone/salmeterol)	Non-preferred inhaled corticosteroid combinations may be approved for members meeting both of the following criteria: • Member has a qualifying diagnosis of asthma or severe COPD; AND • Member has failed two preferred agents (Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.) **TRELEGY ELLIPTA** (fluticasone furoate/umeclidinium/vilanterol) may be approved if the member has trialed/failed three preferred inhaled corticosteroid combination products AND Spiriva. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.

Phosphodiesterase Inhibitors (PDEIs)		

No PA Required	**PA Required**
	
	DALIRESP (roflumilast)
		DALIRESP (roflumilast) may be approved for members when the following criteria are met:
		
		• Member has severe COPD associated with chronic bronchitis and a history of COPD exacerbations (2 or more per year) AND
		• Member must be ≥ 18 years of age AND
		• Member must have failed a trial of TWO of the following (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
		  ○ A long-acting beta2 agonist
		  ○ A preferred inhaled anticholinergic or anticholinergic combination product
		• AND
		• Member does not have moderate to severe liver disease (Child Pugh B or C)