HCPF Response to RFI #4

Discussion of Specialty Drugs, Their Costs and Provider Reimbursement

November 1, 2023

Submitted to: Joint Budget Committee of the Colorado General Assembly

Department of Health Care Policy and Financing, Medical Services Premiums – The Department is requested to submit a report by November 1, 2023, discussing specialty drug costs and reimbursements to providers. The report should include the percent of cost paid for specialty drugs, how the amounts were determined, and how they have changed over time. The report should address both the historic and appropriate settings for administering specialty drugs. The report should discuss projections for specialty drug costs and emerging policy issues.

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I. Executive Summary

Specialty drugs are often used to treat rare or complex disease states. They may require specialized handling, administration, and/or dosing. Specialty drugs now serve as a leading driver of rising presciption drug costs as well as the overall cost of healthcare in the US.

Outpatient retail and mail-order pharmacy specialty drugs are dispensed directly to Health First Colorado members in the traditional retail pharmacy setting. They are reimbursed based on multiple benchmarks to approximate pharmacy acquisition cost. Average Acquisition Cost (AAC) and National Average Drug Acquisition Cost (NADAC) are reimbursements designed to reimburse typical invoice cost to the pharmacy. These drugs are usually self-administered or given by a healthcare provider in the member's home. The net expenditure projection in Medicaid for FY 2023-24 is $460,238,315 plus $2,040,761 for newly approved drugs and for FY 2024-25 is $533,324,159 plus $2,662,511 for newly approved drugs.

Physician administered specialty drugs must be administered by a healthcare professional in the clinic setting. Their reimbursement is set at the federal benchmark of Average Sales Price plus 2.5% to approximate acquisition cost. These drugs are appropriately administered in the clinic setting because special administration technique or post dose observation may be required. Net expenditure projections for FY 2023-24 is $105,829,922 plus $885,680 for newly approved drugs and for FY 2024-25 is $119,841,804 plus $2,510,000 for newly approved drugs.

Outpatient hospital specialty drugs have historically been reimbursed through a bundled payment methodology. The methodology used by the Department is created by 3M and is called Enhanced Ambulatory Patient Grouping (EAPG). The methodology identifies outpatient hospital services and supplies typical to specific visit types and calculates reimbursement based on payment bundles. EAPG implementation rates were intended to reimburse 72% of cost, consistent with the payment methodology used prior to the EAPG reimbursement model, as defined in Colorado regulations. A hospital outpatient facility is the appropriate setting for these drugs due to specialized administration requirements and/or the need for specialized equipment. Projected fiscal changes cannot be calculated by the Department because they are developed and updated by 3M.

Hospitals can request a carveout from the Department for specialty outlier drugs with costs which cannot be absorbed into the EAPG existing bundled payment averages. Under this process, the drug reimbursement has historically varied from 72% of net invoice cost to 90% plus an additional CHASE fee component which varies from approximately 5% to 14%, decreasing as the percent of reimbursement grows. The net expenditure projections for FY 2023-24 are $7,763,807 plus $48,888,529 for newly approved drugs; FY 2024-25 are $8,791,735 plus $90,216,577 for newly approved drugs. Projections for individual drugs administered in the hospital setting may be fluid between inpatient and outpatient settings as both manufacturers and clinicians establish the most appropriate setting for patients.

Hospitals administer and receive Reimbursement for inpatient hospital specialty drugs through a bundled payment methodology. The Department uses the All Patient Refined Diagnosis Related Groups (or APR-DRGs) methodology in the determination of hospital payment for an inpatient hospital stay. It reimburses for each total inpatient stay based on the expected resource intensity assigned to groupings of diagnosis codes. Inpatient administration of specialty drugs is often appropriate due to member risk factors, specialized administration, required supervision and post dose care requirements.

The net expenditure projections for inpatient specialty drugs carved out from DRG reimbursement in FY 2023-24 are $15,170,182; FY 2024-25 are $77,831,719. Carving out outlier specialty drugs from the inpatient bundled payment is currently under development. The target is a reimbursement of 97% of net invoice cost, and 100% of net invoice for drugs provided by a sole pediatric qualified center. The projected effective date of this change is January 1, 2024, pending CMS approval.

This 97% of net invoice reimbursement methodology for carved out specialty drugs dispensed in the hospital setting compares to a 2021 average 81% reimbursement of hospital costs for all other Medicaid hospital payments, including the impact of the CHASE fee.

II. What are Specialty Drugs?

The subset of drugs referred to as “specialty drugs” are typically used to treat rare or complex disease states. Based upon special handling requirements, the need for individualized dosing, specialized administration, premixing or

reconstitution, these drugs often are only supplied by a limited distribution network. Specialty drugs are a leading driver of rising prescription drug costs as well as overall healthcare costs in the US.

Looking specifically at the Health First Colorado population, this is evident in the fact that specialty drugs account for 48% of the pharmacy spend but make up only 1% of pharmacy claims.[1] Said another way, about 1% of drugs dispensed to Medicaid members are so expensive that they are consuming almost 50% of Medicaid drug spend. In 2022, the FDA approved 37 new drugs, 20 of which were for the treatment of rare disease.[2] Since August 2022, five drugs have been approved at prices greater than $2 million per dose (Zynteglo, $2.8 million; Skysona, $3 million; Hemgenix, $3.5 million; Roctavian, $2.9 million; and Elevidys, $3.2 million. All prices noted herein are list prices, not Medicaid prices; federal policy lowers Medicaid reimbursements, through "best price" mandates and manufacturer rebate requirements. Federal requirements prohibit HCPF from disclosing our net reimbursements). An industry focus on treatments for rare and complex diseases has greatly increased the number of available therapies. While specialty drugs are dispensed in all treatment settings, the most complex drugs are dispensed in the hospital setting. Per the Department's federally approved State Plan, specialty drug reimbursement varies depending on the setting. Below we outline four different settings and their related reimbursements, the appropriate settings for administration, and net expenditure projections for future specialty drug costs and policy.

III. Outpatient Retail and Mail-Order Pharmacy Specialty Drugs

Outpatient retail and mail-order pharmacy specialty drugs include those typically dispensed directly to the member via a retail pharmacy, a specialty pharmacy or a mail-order pharmacy. In this setting, the federally approved reimbursement is based upon the lowest value comparing a pharmacy's submitted ingredient cost, a pharmacy's usual and customary charge, the listed Colorado Medicaid Average Acquisition Cost (AAC), the National Average Drug Acquisition Cost (NADAC), or if neither AAC nor NADAC is available, the Maximum Allowable Cost (MAC). The

[1] Reducing Prescription Drug Costs in Colorado – 2nd Edition; January 2021. https://hcpf.colorado.gov/publications

[2] Research, C. for D. E. and. (2023). New drug therapy approvals 2022. FDA. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2022

Department has a dedicated actuary vendor, Myers and Stauffer, who collects invoice cost data to determine AAC values. They also provide a process through which a pharmacy can request AAC reviews when their purchase price exceeds the AAC. Historically, only drugs that are self-administered or administered by a health care professional in the member's home are covered as retail and mail-order pharmacy drugs. Upon the passage of HB 21-1275, long-acting injectable medications for mental health or substance use disorder became eligible for coverage through retail and mail-order pharmacy, even if given in the provider's office.

The outpatient retail and mail-order pharmacy benefit is designed to appropriately cover those drugs that the member self-administers or receives in their home or long-term care setting. This helps to avoid the risk of double billing with physician administered drugs (the pharmacy provides the drug and bills for it, while the medical office bills for the drug again when administering). The projected expenditure for pharmacy retail and mail-order specialty drugs is expected to increase from $397,168,032 in FY 2022-23 to $460,238,315 (with an additional $2,040,761 for drugs in the pipeline) in FY 2023-24 and to $533,324,159 (with an additional $2,662,511 for drugs in the pipeline) in FY 2024-25.

IV. Physician Administered Specialty Drugs

Physician administered specialty drugs (specialty PADs) are those typically administered by a medical professional in a clinic setting. In this setting, the provider's office purchases the drug and bills for both the administration of the drug and the cost of the drug itself. CMS publishes a file which contains the Average Sales Price (ASP) plus 6%, 3.3% is subtracted from these published rates to obtain ASP plus 2.5%. The federally approved reimbursement for such drugs is based upon either the federal benchmark of ASP plus 2.5% if it is available or Wholesale Acquisition Cost (WAC) to approximate acquisition cost. These drugs are appropriately administered in a provider's office or clinic setting without the use of specialized equipment such as an IV infusion pump. Individual drugs of note that are currently impacting expenditure for this setting include: Vyjuvek (estimated $870,000 starting in FY 2024-25); Leqembi (estimated $264,000 in FY 2023-24); Xenpozyme (estimated $162,000 in FY 2023-24); Amvuttra (estimated $96,000 in FY 2023-24); and Enjaymo (estimated $174,000 in FY 2023-24). All prices noted herein are list prices, not Medicaid prices; federal policy lowers Medicaid reimbursements, through "best price" mandates and manufacturer rebate requirements. Federal requirements prohibit HCPF from disclosing our net

reimbursements Expenditure for specialty PADs is projected to increase from $93,456,307 in FY 2022-23, to $105,829,922 (with an additional $885,680 for drugs in the pipeline) in FY 2023-24 and to $119,841,804 (with an additional $2,510,000 for drugs in the pipeline) in FY 2024-25.

V. Outpatient Hospital Reimbursement – EAPG

Reimbursement for specialty drugs in the outpatient hospital setting has historically been achieved through a bundled payment methodology. The Department's bundled payment methodology is created by 3M and is called the Enhanced Ambulatory Patient Grouping (EAPG). This methodology is used currently by twelve Medicaid programs and eight major commercial payers. The EAPG defines different visit types and calculates a bundled payment inclusive of provider resources, supplies, drugs and testing appropriate to that visit type. The bundled payment encourages provider efficiency by minimizing the provision of redundant services. At the time of implementation in October 2016, the methodology was benchmarked to 72% of costs, and it has been significantly adjusted since then. Prior to 2016, outpatient hospital payments were performed on an interim basis and then later reconciled to a percent of each hospital's audited costs. The percent of costs ranged between 68.8% and 72% as defined in Colorado regulations. The EAPG methodology helps to standardize the variable hospital reimbursement rates by averaging costs from many providers for grouped services. The appropriate setting for these drugs is the hospital outpatient facility due to specialized administration requirements and/or the need for specialized equipment. Projected changes to expenditure cannot be quantified by the Department because the rates are developed by 3M and updated by 3M through their proprietary tool in response to changing market conditions. The current 3M methodology uses historic claim and cost data to calculate prospective payment rates. Specialty drugs (especially those with costs well outside of historical averages) that entered the market after the historical data period are not properly reflected and therefore not properly paid in the current EAPG model.

VI. Outpatient Hospital Drug Reimbursement – Specialty Carveout

Reimbursement for outpatient hospital drugs outside of bundled EAPG payment became a necessary solution for select specialty drugs in 2018, in response to specialty outlier drugs with costs which could not be absorbed into the existing bundled payment averages (e.g., Zolgensma which was priced at $2.1 million, list price). In response to stakeholder discussions, the Department developed a

process and obtained federal authorization to allow the carveout of specific drugs to address unrealistic reimbursements for emerging specialty drugs Initially, the carveout reimbursement provided payment at 72% of net invoice cost to retain budget neutrality with the 72% benchmark for outpatient hospital reimbursement. The addition of CHASE fee funds later brought this reimbursement up to a level around 84% of net invoice cost. Further discussion with hospital stakeholders brought about a revised reimbursement during the COVID pandemic (February 2021), allowing payment at 90% of net invoice cost, which is nearly 95% with the inclusion of CHASE fee. Pending federal approval for early 2024, the Department intends to increase reimbursement to 97% of net invoice cost for these providers, only on approved carve out drugs. The outpatient hospital setting for drug administration is appropriate for those therapies which require specialized administration techniques, specialized equipment, a sterile setting and/or monitoring post administration due to higher risk of adverse reactions. This category of drugs does not require an inpatient stay or inpatient level services.

It is increasingly more common for newly approved drugs and drugs in the pipeline to require the outpatient hospital setting for administration, especially when targeting rare disease. Expenditure for the specialty drugs carved out of EAPG reimbursement in FY 2022-23 was $6,856,064. Projected expenditure for FY 2023-24 is expected to be $7,763,807 with an additional $48,888,529 for pipeline drugs approved during the fiscal year. It is expected that for FY 2024-25, the expenditure will be $8,791,735 for currently available drugs, plus an additional $90,216,577 for specialty drugs anticipated to gain FDA approval. Projections for individual drugs administered in the hospital setting may be fluid between inpatient and outpatient settings as both manufacturers and clinicians establish the most appropriate setting for patients.

VII. Inpatient Hospital Drug Reimbursement – APR DRG

Like outpatient hospital specialty drugs prior to their carveout, payment for inpatient specialty drugs is achieved through a bundled payment methodology. The Department uses the All Patient Refined Diagnosis Related Groups (or APR-DRGs) methodology in the determination of hospital payment for an inpatient hospital stay. This methodology is developed and maintained by 3M Health Information Systems. Unlike the EAPG methodology used in the outpatient setting, however, the APR-DRG methodology achieves payment through classification of an inpatient stay based on the diagnosis codes present on the hospital claim. Such classifications are based on 3M's groupings of similar

diagnosis codes, with each grouping being assigned a numerical value describing the expected resource intensity for treating the inpatient, which is ultimately used in calculating payment. As payment through APR-DRG is intended to accommodate the expected resource utilization required for the full inpatient stay, with the expected utilization being derived from historical data, services provided during the stay are not individually reimbursed and the costs of new-to-market drugs are ultimately not factored into the payment. Despite that, inpatient administration for many drugs is appropriate and often required based upon risk factors, specialized administration, and/or required supervision and care post administration.

VIII. Inpatient Hospital Drug Reimbursement – Specialty Carveout

Carving out outlier specialty drugs from the inpatient bundled payment is currently under development. Modification of the inpatient payment policies will require federal approval of a State Plan Amendment as well as a related rule change which will require approval by the Medical Services Board. The Department intends to reimburse specialty drugs at 97% of net invoice cost, or 100% of net invoice cost when provided through qualifying sole pediatric treatment centers. Expenditure for specialty drugs carved out of APR-DRG reimbursement in FY 2023-24 is expected to be $15,170,182 and in FY 2024-25, $77,831,719. With such a strong pipeline for specialty drugs which will require inpatient administration, this will be a large area of growth in drug spend over the coming years. Projections for individual drugs administered in the hospital setting may be fluid between inpatient and outpatient settings as both manufacturers and clinicians establish the most appropriate setting for patients.

IX. Summary

The prescription drug landscape is undergoing major changes, and this is only the beginning. The industry has a new focus on treating rare and complex diseases via cell and gene therapy. Current innovation is making therapy available for diseases that were previously untreatable. The impact of innovations are also lesspredictable, as the clinical trial populations are small and the durability of one time gene therapy treatments are unknown. The drug expenditure for the Medicaid program is expected to continue rising over the coming years. Many of these innovations have the potential to lower healthcare costs in other areas and provide great increases in quality of life. The balance of keeping new therapies accessible to those who need them, while containing rising prescription drug costs

and maintaining value for public funding is a focus for the Department of Health Care Policy and Financing. Collaboration and compromise has been an important part of this effort as our stepwise approach to solving this problem has shown.