May 6, 2019

To: Kim Bimestefer, Executive Director
Colorado Department of Health Care Policy & Financing
1570 Grant Street · Denver, CO 80203-1818

Cc: Felecia Gephart, MHA, Physician Administered Drug Benefit Manager
Laurel Karabatsos, Delivery System and Payment Innovation Division Director
Cathy Traugott, Pharmacy Section Manager
Sarah Rogers, State Medical Assistance & Services Advisory Council
Chris Sykes, Medical Services Board Coordinator
Colorado State Senators and Representatives

RE: JW Modifier non-reimbursement for wastage

To Whom It May Concern:

The stakeholders signing on to this letter applaud the Colorado Department of Healthcare Policy and Financing's (HCPF) efforts to reduce healthcare costs for the state. However, an arbitrary policy decision has led to devastating, unintended consequences for Medicaid members, potentially resulting in poor healthcare outcomes, increased costs, and reduced quality of life. Discussions with HCPF have been unsuccessful to date and we are now asking for a reversal of this policy.

On page 10 of the May 2018 Bulletin, Reference: B1800415 (Appendix A), HCPF states:

> Health First Colorado does not reimburse for any drug which is discarded or not administered to a Health First Colorado member. The amount of PAD administered to a Health First Colorado member must be documented in the member's medical record and the provider must only bill for this amount.
>
> An exception to this rule is in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 17, section 40. This policy states that claims for Part B drugs and biologicals are required to use the JW modifier to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. Both the amount administered and discarded must be noted in the member's medical record.
>
> Therefore, Health First Colorado will reimburse for PADs discarded/not administered to any member with the JW modifier for Medicare Crossover claims only. Also, multi-use vials are not subject to payment for discarded amounts of drug or biological.

There are several problems with this policy.

1. It is not in accordance with the Medicare Claims Processing Manual, as noted in the May Bulletin.
2. It discriminates between Medicaid and dual-eligible Medicaid patients, creating two levels of care.
3. It is not supported by the Code of Colorado Regulations 10 CCR 2505-10 8.000 (Appendix B) cited by Felicia Gephart (Appendix C).
4. It was announced in May of 2018 due to an oversight error on HCPF's part (found during the transition from Xerox to HP) and was implemented retroactive to 1/1/2017, causing substantial financial harm to healthcare providers.

5. It puts healthcare providers in an impossible situation, forcing them to choose one of the following:
    a. Round up or down to the nearest vial (this is clinically unsound).

    b. Use single-dose vials multiple times (there is no clinical evidence to support the safety of this practice).
        i. This practice is commonly referred to as drug vial optimization (DVO). This involves the unsupported practice of using closed-system transfer devices (CSTDs) to transform a single-dose vial into a multi-dose vial, despite the lack of necessary preservatives to prevent microbial contamination that may result from multiple uses of the product. Some practices across the country are starting to utilize this method to prevent waste and/or reduce cost, which could lead to patient harm. When used correctly, these safety devices are meant to prevent the spread of drug contamination only, not to extend the shelf life of these drugs. The lack of adequately powered studies and primary literature supporting the practice of DVO has led to trusted organizations such as the FDA, the U.S. Pharmacopeia and the Joint Commission to denounce this practice.
    c. Refer the patients to a different site of care, creating disruptions in care, increased costs, and poor disease management.
    d. Not report the amount of wastage, thus committing fraud.

    e. Refuse to treat the patient.

The medical benefit drugs implicated by this policy change are used to treat a wide breadth of complex, chronic, rare, difficult-to-treat, and/or life-threatening diseases (Appendix C) that represent some of the most expensive and challenging conditions to manage with incredibly high physical, emotional, and economic burden of disease. The use of these drugs to treat these conditions is medically necessary as conventional drugs have been ineffective or contraindicated. The management of some of the state's most vulnerable citizens with these drugs in outpatient care settings is reducing cost-burden for these patients as well as the state's Medicaid program. However, this policy change would reduce the financial viability of treating these patients in the office. As such, these patients—and a large increase in Medicaid drug spend—will have to be managed in hospital-based care settings at a significant increase in immediate-term per patient per treatment costs, or undermanaged at an even greater increase in non-drug medical spend.

We welcome the opportunity to discuss this issue. Should you have any questions or require additional information, please contact April Christensen, Executive Director of the Coalition of Hematology and Oncology Practices at chop@choptx.org, or Brian Nyquist, Executive Director of the National Infusion Center Association at brian.nyquist@infusioncenter.org.

Sincerely,

Coalition of Hematology and Oncology Practices
National Infusion Center Association
Aimed Alliance
Community Oncology Alliance
Rocky Mountain Cancer Centers
American College of Rheumatology

Appendix A: Provider Bulletin Reference: B1800415

https://www.colorado.gov/pacific/sites/default/files/Bulletin_0518_B18004115.pdf

Appendix B: Code of Colorado Regulations, 10 CCR 2505-10 8.000

8.076.1 DEFINITIONS

1. Abuse means Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medical Assistance program, an overpayment by the Medical Assistance program, or in reimbursement for goods or services that are not medically necessary, as defined at 8.076.1.8., or that fail to meet professionally recognized standards for health care. These practices may include, but are not limited to:

a. Billing for goods or services without valid documentation to support the claims submitted for reimbursement.

8. Medical necessity means that a Medical Assistance program good or service:

a. Will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, condition, injury, or disability. This may include a course of treatment that includes mere observation or no treatment at all.

d. Is not primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider;

Appendix C: 8/14/18 email from Felicia Gephart

Not paying for waste/discarded drugs has always been the Health First Colorado policy for PADs. It was discovered that the previous claims processing system was not enforcing this policy, so the May bulletin was published as a reminder to providers. At this time, under Colorado Medicaid rules and regulations, providers must provide services which are medically necessary and are to bill for only the amount of drug administered to the Medicaid member.
Please refer to the following rules:
10 CCR 2505-10, Section 8.076.1.1a
10 CCR 2505-10, Section 8.076.1.8a
10 CCR 2505-10, Section 8.076.1.8d

Appendix D: Non-exhaustive list of the indications that may be implicated by this policy decision:

- Rheumatoid Arthritis
- Crohn's Disease
- Ulcerative Colitis
- Psoriasis
- Psoriatic Arthritis
- Ankylosing Spondylitis
- Systemic lupus erythematosus
- Sjögren's Disease
- Grave's Disease

- ☐ Mysthenia Gravis
- ☐ Multiple Sclerosis
- ☐ Amyotrophic lateral sclerosis (ALS)
- ☐ Eosinophilic Asthma
- ☐ Immunodeficiencies
- ☐ Cancers
- ☐ Hemophilia and bleeding disorders (e.g. immune thrombocytopenia)
- ☐ Iron deficiency anemia in people with chronic kidney disease
- ☐ Hypereosinophilic syndrome
- ☐ Severe infections
- ☐ Dermatomyositis
- ☐ Diabetes
- ☐ Treatment-refractory gout
- ☐ Fabry disease
- ☐ Osteoporosis
- ☐ Metabolic disorders
- ☐ Severe chronic migraine
- ☐ Major depressive disorder