REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-15

Subject: Parity of Payment for Administering Biologic Medications (Resolution 218-I-14)

Presented by: Robert E. Hertzka, MD, Chair

Referred to: Reference Committee J (Jeffrey P. Gold, MD, Chair)

At the 2014 Interim Meeting, the House of Delegates referred Resolution 218, "Parity of Payment for Administration of Medications within the Same Category of Drug," which was sponsored by the American College of Rheumatology, American Academy of Allergy, Asthma and Immunology, and the American Gastroenterological Association. Resolution 218-I-14 asked:

> That our American Medical Association (AMA) use its influence and resources to secure Congressional outreach to the Centers for Medicare and Medicaid Services (CMS) with the objective that CMS issue guidance requiring parity of payment for administration of medications within the same category of drug.

This report provides background on the concerns raised in Resolution 218-I-14, explains Medicare's process for developing local and national coverage determinations (NCDs), outlines the development of current procedural terminology (CPT®) codes for the administration of biologics, reviews CPT Editorial Panel activities, summarizes relevant AMA policy, discusses the appropriate avenue for addressing payments by Medicare for biologics, and provides policy recommendations.

BACKGROUND

Resolution 218-I-14 states that several Medicare Administrative Contractors (MACs) do not cover all biologics as complex injections or infusions when administered to patients with rheumatic diseases, while other MACs do. In separate communication with the Council, the resolution's sponsors assert that inconsistent payments by MACs for biologics result in geographic disparities in access to care and are seeking a NCD directing Medicare Administrative Contractors (MACs) to uniformly pay for all biologics for rheumatic conditions under the complex chemotherapy administration codes (96401-96549).

At the 2014 Interim Meeting, the reference committee recommended that Policy H-390.921 be reaffirmed in lieu of Resolution 218. Policy H-390.921 advocates for uniformity of business policies and procedures among MACs. While some testimony agreed that Policy H-390.921 addresses the concerns raised by Resolution 218-I-14, it was referred due in part to disagreement about whether all biologics could be considered equal with respect to administration and payment. Of additional concern is that the outcome of requesting CMS to review and possibly issue a NCD is uncertain. Payments for the administration of biologics could be uniformly increased or decreased.

© 2015 American Medical Association. All rights reserved.

MEDICARE ADMINISTRATIVE CONTRACTORS

Medicare uses an evidence-based process to make NCDs. If a national coverage policy does not exist or if there is a need to further define NCDs, MACs are responsible for developing local coverage determinations (LCDs). Since there is no national coverage policy for the administration of biologics to patients with rheumatic conditions, MACs have developed LCDs, resulting in inconsistent payments among MACs for these medications.

CODING AND PAYMENT FOR BIOLOGICS

In the AMA's 2015 CPT codebook, administration codes for biologics include three categories: hydration, therapeutic and chemotherapy.[1] These codes are intended to reflect differences in the physician work and other resources needed to administer biologics depending on the therapeutic need. Specifically, the CPT Editorial Panel has defined the differences in each category in terms of physician work, staff work and training, and patient risk. In general, the degree to which these factors impact the administration of biologics is less for hydration infusion services and progressively increases for therapeutic infusions and chemotherapy infusions. Preceding each category of infusions in the AMA's 2015 CPT® codebook, introductory text defines the physician work, staff training and work, and patient risk, to assist users in applying the codes. Therefore, payment is dependent on the factors impacting the administration of the infusion or injection and cannot be determined uniformly for a specific drug.

Current CPT codes for the administration of infusions and injections were developed by the CPT Editorial Panel in 2004. A CPT Editorial Panel Drug Infusion Workgroup (Workgroup), which included representatives from the sponsor organizations of Resolution 218-I-14, developed CPT code revisions and clarifications over the course of six years. During the Workgroup's May 2006 conference call, it was decided that a revision would be proposed to the CPT Editorial Panel for review by the specialties that chemotherapy administration guidelines in the CPT codebook should clarify the difference between the therapeutic injection codes and the chemotherapy administration codes. To make this distinction, the CPT Editorial Panel decided to add the word "certain" to the guidelines to convey that not all monoclonal antibodies, only certain ones, require use of the complex infusion administration codes.

The biologics identified in Resolution 218-I-14, Rituximab and Infliximab, are monoclonal antibodies that the resolution's sponsors have found to be considered complex injections or infusions by MACs, and therefore covered as such. Other monoclonal antibodies may not be considered complex if a MAC has made a determination that the infusion does not require complex services and instead belongs in the therapeutic infusion services category.

CPT EDITORIAL PANEL ACTIVITIES

Board of Trustees Report 10-A-07, "Development of a Drug Classification Advisory Panel," considered the development of an AMA-sponsored drug classification advisory panel to facilitate appropriate use of CPT drug administration codes.[2] Through a feasibility study conducted by an outside consultant, it was determined that an AMA-sponsored drug classification advisory panel would present legal risk to the AMA, largely because the development of drug products is a high-stakes venture in which classification decisions potentially have million-dollar ramifications. Of specific concern was that a drug manufacturer could potentially seek judicial review if it does not agree with a classification decision.

Board Report 10-A-07 established Policy D-70.956, directing the AMA to ask the CPT Editorial Panel to develop educational material to assist users in the application of CPT drug administration codes. This directive was accomplished by the CPT Editorial Panel publishing numerous articles in the CPT Assistant Newsletter, a publication that provides in-depth information on how to code accurately and efficiently. Policy D-70.956 also directed the AMA to request the CPT Editorial Panel to consider revisions to the existing drug administration codes to add enhanced section and subsection headings, guidelines and parenthetic references, with the intention of assisting users in the application of the codes. The suggested revisions were made. The AMA continues to monitor the issue of drug classification within CPT drug administration code categories for physician billing and claims problems.

The AMA identifies the CPT Editorial Panel as the proper forum for addressing CPT codeset maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers (Policy H-70.919).

The AMA continues to support taking all appropriate measures, including meetings if necessary, to ensure that no CPT Editorial Panel updating process proceeds without providing for input from knowledgeable physicians and other stakeholders, including a cross-section of affected and related specialties, to allow these physicians to carefully review all changes suggested for inclusion in CPT prior to their acceptance (Policy H-70.998).

It is the policy of the AMA that the CPT Editorial Panel continue its policy of not making coding decisions that are influenced by economic or budgetary considerations. It is the responsibility of the AMA/Specialty Society Relative Value Scale Update Committee (RUC) to consider implementation issues such as economic factors when it recommends work values for new and revised CPT codes (Policy H-70.966).

ADDITIONAL RELEVANT AMA POLICY

The Council addressed payment for biologics and pharmacologic agents in its Report 3-I-08, "Payment for Biologics and Pharmacologic Agents," which established policy supporting Medicare payments for drugs to fully cover the physician's acquisition, inventory, carrying cost, administration and related services, and to be adequate to ensure continued patient access to biologic and pharmacologic agents[3] (Policy D-330.960).

In accordance with Policy H-390.921, the AMA supports uniformity of business policies and procedures among MACs and monitors differences in payment to physicians by MACs. The AMA works to identify outdated coverage decisions that create obstacles to clinically appropriate patient care and advocates that NCDs and LCDs should reflect available scientific evidence and contemporary practice. The AMA encourages the Federation to report problems with MACs, or other Medicare contractors, to the AMA (Policy D-330.943).

DISCUSSION

The Council agrees with the concerns raised in Resolution 218-I-14 that access to care can be compromised if biologics for rheumatic diseases are not uniformly paid for by all MACs.

The Council notes, however, that the CPT codebook considers only certain biologics administered for rheumatic diseases to require the use of the chemotherapy administration codes. The Council suggests reaffirming Policy H-70.919, which directs interested stakeholders to use the CPT

Editorial Panel process to request revisions in CPT codes, descriptors, guidelines, parenthetic statements and modifiers.

Submitting a request to CMS for a NCD that directs MACs to uniformly pay for all biologics used for rheumatic diseases under the complex chemotherapy administration codes, as requested by Resolution 218-I-14, is a formal process outlined in the notice issued by CMS concerning the revised process for making national coverage determinations.[4] The request must clearly identify the statutorily defined benefit category to which the requester believes the service applies and contain enough information for Medicare to make a benefit category determination; be accompanied by sufficient, supporting evidentiary documentation; address relevance, usefulness or the medical benefits of the service to the Medicare population; and fully explain the design, purpose and method of using the service for which the request is made.[5]

The formal submission process requires detailed clinical and specialty-specific knowledge of the requested services, which the AMA cannot provide. Accordingly, the Council supports and encourages interested national medical specialty societies and other stakeholders to submit a request to Medicare for a NCD directing MACs to consider all biologics as complex injections or infusions for rheumatic conditions.

The Council also recommends reaffirming Policy H-390.921, indicating that the AMA supports uniformity of business policies and procedures among MACs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 218-I-14 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-390.921, which advocates for uniformity of business policies and procedures among Medicare Administrative Contractors. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-70.919, which identifies the Current Procedural Terminology (CPT®) Editorial Panel process as the proper forum for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers. (Reaffirm HOD Policy)

3. That our AMA support and encourage interested national medical specialty societies and other stakeholders to submit a request to Medicare for a national coverage determination directing Medicare Administrative Contractors to consider all biologics as complex injections or infusions. (New HOD Policy)

Fiscal Note: Less than $500.

REFERENCES

[1] American Medical Association. American Medical Association 2015 Current Procedural Terminology (CPT®) codebook. Copyright 2015. All rights reserved.
[2] American Medical Association. Board of Trustees Report 10-A-07. Development of a Drug Classification Advisory Panel. 2007.
[3] American Medical Association. Council on Medical Service Report 3-I-08. Payment for Biologics and Pharmacologic Agents. 2008. Available at: file:///C:/Users/dberthma/Downloads/cms3-i08biologics%20(2).pdf
[4] Federal Register Notice: Medicare Program; Revised Process for Making National Coverage Determinations. 2013. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf
[5] Notice on Medicare Program; Revised Process for Making National Coverage Determination, Federal Register. 48164-48169. (August 7, 2013). Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf