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#### Headquarter Office

Ann Marie Moss Executive Director May 26, 2021

Robert E. Kettler, MD Ella M. Noel, D.O., F.A.C.O.I. Wisconsin Physicians Service Insurance Corporation 1717 W. Broadway PO Box 1787 Madison, WI 53701-1787

## RE: Local Coverage Article (LCA) titled Billing and Coding: Complex Drug Administration (A58544)

Dear Drs. Kettler and Noel:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

We write to share concerns about your recently revised LCA that provides billing and coding guidance for complex drug administration based on the assertion that "there is inappropriate use of CPT codes 96401-96549 for chemotherapy and other highly complex drug or highly complex biologic agent administration."<sup>i</sup>

#### Challenges with LCA Policy

As the LCA explains, the American Medical Association (AMA) Current Procedural Terminology (CPT) code book describes chemotherapy as including "other highly complex drugs or highly complex biologic agents," that in the context of chemotherapy administration (CPT 96401-96549) would consist of "certain monoclonal antibody agents, and other biologic response modifiers."<sup>iii</sup> The AMA CPT code book further clarifies that these drugs require advanced clinical skill to prepare, administer, and monitor, given the associated safety warnings and potential for adverse reactions.

Moreover, CMS previously issued a one-time notification<sup>iii</sup> to its Medicare Administrative Contractors (MACs) that stating the following:

"...chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumab, gemtuzumab, and trastuzumab."

The notice was issued in December 2004 when there were only a handful of targeted therapies available for non-cancer diagnoses. Since that time, however, there has been tremendous growth in the availability of monoclonal antibody agents and other biologic response modifiers for use in autoimmune diseases, such as rheumatoid and psoriatic arthritis.

Based on the above, it is clear that targeted therapies used to treat rheumatic conditions, including Cimzia<sup>®</sup>, Prolia<sup>®</sup>, Orencia<sup>®</sup>, Simponi Aria<sup>®</sup>, and Stelara<sup>®</sup>, are highly complex drugs

*and biologic agents.* Coding for the administration of these therapies squarely fits the definition of "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration" (CPT codes 96401 – 96549). Unfortunately, the LCA concludes otherwise and directs clinicians to inappropriately "down-code" the administration of these drugs using "Therapeutic Prophylactic, and Diagnostic Injections and Infusions" codes (CPT codes 96365 – 96379).

## Challenges with LCA Process

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- 4) Failed to meet the evidentiary content requirement required in every proposed LCD; and,
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#### Conclusion

*We strongly oppose NGS' revised coverage policy for complex drug administration*, as described in the aforementioned LCA. Moreover, we are deeply disappointed in the process used to establish this coverage policy by unilaterally issuing an LCA. This is not in the spirit of the transparency and increased stakeholder engagement intended by Congress in revising the LCD process by way of the 21<sup>st</sup> Century Cures Act, nor of CMS' improvements to the LCD process following stakeholder feedback to its Request for Information (RFI) in the CY 2018 Physician Fee Schedule. *We urge you to withdraw this billing and coding article, or, at a minimum, eliminate the aforementioned drugs from the policy.* 

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Michael C. Schweitz, MD Federal Advocacy Chair

<sup>&</sup>lt;sup>i</sup> <u>https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=58620&ver=6</u>

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Leland Garrett, MD, FACP, FASN, CPC Miguel Brito, MD, FCAP, FASCP Palmetto GBA Attn: Medical Affairs, AG -275 P.O. Box 100305 Columbia, SC 29202-3305

## RE: Local Coverage Article (LCA) titled Billing and Coding: Complex Drug Administration (A58527)

Dear Drs. Garrett and Brito:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

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Based on the above, it is clear that targeted therapies used to treat rheumatic conditions, including Cimzia<sup>®</sup>, Prolia<sup>®</sup>, Orencia<sup>®</sup>, Simponi Aria<sup>®</sup>, and Stelara<sup>®</sup>, are highly complex drugs

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#### May 26, 2021

Eileen Moynihan, MD, FACP, FACRh Janet Lawrence, MD Noridian Healthcare Solutions, LLC 900 42nd Street S. PO Box 6781 Fargo, ND 58103-6781

## RE: Local Coverage Article (LCA) titled Billing and Coding: Complex Drug Administration (A58532 and A58533)

Dear Drs. Moynihan and Lawrence:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

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The notice was issued in December 2004 when there were only a handful of targeted therapies available for non-cancer diagnoses. Since that time, however, there has been tremendous growth in the availability of monoclonal antibody agents and other biologic response modifiers for use in autoimmune diseases, such as rheumatoid and psoriatic arthritis.

Based on the above, it is clear that targeted therapies used to treat rheumatic conditions, including Cimzia<sup>®</sup>, Prolia<sup>®</sup>, Orencia<sup>®</sup>, Simponi Aria<sup>®</sup>, and Stelara<sup>®</sup>, are highly complex drugs

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Ann Marie Moss Executive Director May 26, 2021

Carolyn Cunningham, M.D. Stephen D. Boren, MD National Government Services, Inc. P.O. Box 7108 Indianapolis, IN 46207

## RE: Local Coverage Article (LCA) titled Billing and Coding: Complex Drug Administration (A58620)

Dear Drs. Cunningham and Boren:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

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Based on the above, *it is clear that targeted therapies used to treat rheumatic conditions, including Cimzia®, Prolia®, Orencia®, Simponi Aria®, and Stelara®, are highly complex drugs and biologic agents.* Coding for the administration of these therapies squarely fits the definition of "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent

Administration" (CPT codes 96401 – 96549). Unfortunately, the LCA concludes otherwise and directs clinicians to inappropriately "down-code" the administration of these drugs using "Therapeutic Prophylactic, and Diagnostic Injections and Infusions" codes (CPT codes 96365 – 96379).

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Michael S. Brooks, MD, FACP, FACR Secretary

# RE: Local Coverage Articles titled Billing and Coding: Complex Drug Administration (A58526)

Dear Dr. Loveless:

May 26, 2021

26 Century Blvd.

Ste. ST610

Meredith Loveless, MD

CGS Administrators, LLC

Nashville, TN 37214-3685

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

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