

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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Food and Drug Administration Approval of First Biosimilar Product

Provider Types Affected

This article is intended for health care professionals who submit claims to Medicare Administrative Contractors (MACs) for Medicare Part B services furnished to Medicare beneficiaries.

What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) is aware that the Food and Drug Administration (FDA) has approved the first biosimilar product. CMS policies will ensure Medicare beneficiaries will have access to this new product, as it does for other drugs that receive FDA approval. The purpose of this article is to address questions that have arisen regarding biosimilar products.

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Questions and Answers About Biosimilar Products

Question:

How will a health care professional that administers this product get reimbursed under Medicare Part B?

Answer:

Medicare Part B payment for newly approved drugs and biologicals is available once the product is approved by the FDA. CMS will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the Average Sales Price (ASP) payment methodology, and issue additional guidance as necessary. Initially, once the manufacturer's wholesale acquisition cost (WAC) is available, Medicare will pay 106 percent of the WAC for the product until ASP information is available. Once ASP information is available for this biosimilar product, Medicare payment will equal the ASP for the biosimilar product plus six percent of the ASP for the reference product.

Question:

How soon will CMS be releasing coding information related to Part B reimbursement?

Answer:

CMS anticipates including the approved biosimilar in the next quarterly Healthcare Common Procedure Coding System (HCPCS) tape release in the coming weeks, appearing in the claims processing system on July 1, 2015, effective retroactively to the FDA approval date.

Question:

Will CMS be assigning unique codes to each biosimilar released?

Answer:

CMS will create a separate code to distinguish the biosimilar from the reference biological. CMS is considering policy options for coding of additional biosimilars, and will release further guidance in the future.

Question:

Will use of a distinguishing identifier to biological products make it harder to achieve Medicare reimbursement?

Answer:

Distinguishing identifiers will have no bearing on coding and payment.

Question:

How will CMS address providing access to biosimilars through Medicare Part D?

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Answer:

Although coverage for filgrastim will generally be provided through Part B, it could also be covered under Part D in certain circumstances (for example, nursing homes or Intermediate Care Facilities for Individuals with Intellectual Disabilities ICF/IID)). CMS will be releasing guidance to plans confirming that biosimilars approved by the FDA will be subject to existing rules for prescription drugs under Part D.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net/work-MLN/MLNMattersArticles/index.html> under - How Does It Work.

Seasonal Flu Vaccinations - For information on coverage and billing of the influenza vaccine and its administration, please refer to [MLN Matters® Article #MM8890](#), “Influenza Vaccine Payment Allowances - Annual Update for 2014-2015 Season” and [MLN Matters® Article #SE1431](#), “2014-2015 Influenza (Flu) Resources for Health Care Professionals.”

Also, check out the following resources from the Centers for Disease Control and Prevention (CDC): [Influenza \(Flu\)](#) web page for the latest information on flu including the CDC 2014-2015 recommendations for the prevention and control of influenza, antiviral information, CDC flu mobile app, Q&As, toolkit for long term care employers, and other free resources. Review the CDC’s [Antiviral Drugs](#) website for information about how antiviral medications can be used to prevent or treat influenza when influenza activity is present in your community, and view the updated “Influenza Antiviral Medications: Summary for Clinicians.” A CDC Health Update reminding clinicians about the importance of flu antiviral medications was distributed via the CDC Health Alert Network on January 9, 2015, and is available at <http://emergency.cdc.gov/HAN/han00375.asp> on the Internet.

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