



September 23, 2022

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Medical Affairs  
Suite 100  
2020 Technology Parkway  
Mechanicsburg, PA 17050

**RE: Proposed Local Coverage Determination (LCD) Immune Globulin (DL35093)**

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed local coverage determination (LCD) for immune globulin (DL35093) posted by the Centers for Medicare & Medicaid Services (CMS) on August 11, 2022.<sup>1</sup> NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and alternate site infusion community, we write to share our feedback on the proposed Immune Globulin LCD.

The immune globulin LCD is being revised to create a uniform LCD with another MAC jurisdiction. CMS notes that the current LCD is limited to intravenous immune globulin (IVIG) use and that the revised LCD will address both subcutaneous and intravenous immune globulin use consistent with indications approved by the Food and Drug Administration (FDA) and those where evidence supports off-label indications. The proposed LCD includes 27 off-label indications for IVIG products that will be considered medically reasonable and necessary and notes that off-label use of subcutaneous immune globulin is not considered medically reasonable and necessary. NHIA supports CMS basing its Medicare coverage policy on evidence-based medicine.

The proposed LCD would include coverage of subcutaneous immune globulin (SCIG), which has been licensed by the FDA for treatment of primary immunodeficiencies (PIs) and treatment of chronic inflammatory demyelinating polyneuropathy (CIPD). A primary advantage of SCIG is to offer patients more flexibility and independence with their immune therapy, which allows for self-administration at home with the support of pharmacists and nurses specially trained in managing patients receiving home infusion therapies. SCIG is covered under the Medicare Part B DMEPOS benefit in conjunction with the home infusion therapy (HIT) services benefit when administered in a patient's home. NHIA notes that SCIG requires a more frequent dosing schedule than IVIG, and would therefore require the beneficiary to travel much more frequently

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<sup>1</sup> <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39431&ver=12&contractorName=6&contractorNumber=all&updatePeriod=1002&sortBy=updated&bc=13>



to a physician's office for administration. Frequent travel can be burdensome and in some cases is not possible for beneficiaries in rural areas, those who don't have reliable transportation, and those with disabilities, which is common for CIDP patients. The advantages of SCIG for CIPD is described in a 2020 review article published in the *Journal of Neurological Sciences* weighing IV and SC administration of immune globulin for the treatment of CIPD.<sup>2</sup>

*“Unlike IVIG which requires administration by a health care professional, subcutaneous immunoglobulin (SCIG) can be self-administered by patients in their home. The flexibility of self-administration may lessen the burden associated with infusions thereby improving a patient's health-related quality of life (HRQoL).”*

NHIA does not believe it is necessary for SCIG coverage to be added to the physician office site of care because beneficiaries traveling to a physician's office for immune globulin therapy benefit from the less frequent IVIG treatment schedule. The vast majority of beneficiaries who choose the SCIG option do so because it can be self-administered in their home, a contributing factor in their health-related outcomes.

If the decision is made to add SCIG coverage in physician offices, it is critical that Medicare beneficiaries be informed of the site of care options available to them (i.e., home, physician's office, or HOPD) as is required per the calendar year 2021 physician fee schedule final rule, which was issued on December 28, 2020.<sup>3</sup>

NHIA appreciates the opportunity to provide comments on these important issues. For questions or additional information, please contact me at [connie.sullivan@nhia.org](mailto:connie.sullivan@nhia.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan", written in a cursive style.

Connie Sullivan, B.S. Pharm  
President and Chief Executive Officer

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<sup>2</sup> Allen J, Gelinas D, Freimer M, Runken MC, et al. Immunoglobulin administration for the treatment of CIDP: IVIG or SCIG? *Journal of Neurological Sciences*. January 15, 2020. Volume 408(116497).

<sup>3</sup> <https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf>