National Home Infusion Association

September 10, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Polices; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks La-Sure:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule: *Medicare and Medicaid Programs; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Polices; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements* (the "Proposed Rule") issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on July 23, 2021.[1] 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 specialty infusion community, we write to share our feedback regarding monoclonal antibodies used to treat COVID-19 and the National Coverage Determination for Enteral and Parenteral Nutritional Therapy.

Monoclonal Antibodies Used to Treat COVID-19

Throughout the public health emergency, home infusion pharmacists and nurses have been playing a critical role in making monoclonal antibody products for COVID-19 available to patients at high risk for contracting severe COVID-19. In December 2020, home infusion providers, in collaboration with the office of the Assistant Secretary for Pandemic Response (ASPR), stepped up to support patients living in long-term care facilities. As part of the Special Projects for Equitable and Efficient Distribution (SPEED) program, home infusion pharmacies demonstrated a willingness to offer their services and expertise to facilities in need of additional support to provide monoclonal antibodies to residents of skilled and assisted living facilities.

[1] 86 Fed. Reg. 39104 (July 23, 2021)

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Prior to CMS's decision on May 6, 2021, to increase reimbursement for home administration of COVID-19 monoclonal antibody treatments from $310 to $750, administering life-saving monoclonal antibody treatments at home was hindered by inadequate reimbursement. NHIA applauds CMS for recognizing the additional costs for providers to serve patients in the home setting and increasing the payment for home-based care, which has resulted in thousands more patients having access to effective treatment for COVID-19. Additionally, home infusion providers have been instrumental in maintaining access to monoclonal antibody treatments in between the surges in COVID-19 cases when hospitals found that maintaining dedicated facility space and staff was inefficient and unnecessary.

Home infusion pharmacies specialize in the safe and effective administration of intravenous therapies, including monoclonal antibodies. They offer physician-ordered infusion services to patients in their homes and in pharmacy-owned and operated infusion suites. Traditionally, these suites are utilized to serve patients with commercial insurance who prefer not to be treated at home or to administer a first dose of a new drug in a more controlled setting. During COVID-19, home infusion providers were able to dedicate their suites to serve additional patients in need of COVID-19 monoclonal antibodies. The ability to utilize pharmacy-owned and operated infusion suites for Medicare beneficiaries eligible for COVID-19 monoclonal antibodies allowed providers to maximize their nursing resources and treat more patients.

NHIA appreciates CMS's efforts to improve access to home infusion of treatments for COVID-19. However, coverage for home-based infusions of monoclonal antibody products for COVID-19 is limited to the duration of the public health emergency and the continued provision of these services at home will not occur without action by CMS to maintain access. Because monoclonal antibody products for COVID-19 do not require the use of an ambulatory infusion pump for administration, there would not otherwise be coverage under the existing Part B home infusion therapy services benefit. Without a continuation of the current or similar flexibilities offered by CMS, home infusion therapy services providers will be sidelined from offering these treatments after the public health emergency ends.

In the Proposed Rule, CMS requested feedback on its approach to coverage and payment for COVID-19 monoclonal antibody products under the COVID-19 preventive vaccine benefit. CMS notes that if it treated monoclonal antibody products for COVID-19 like other drugs and biologics paid under section 1847A of the Social Security Act, beneficiary coinsurance would apply. In addition, this model only covers office and hospital-based infusions and does not allow for administration in the home setting. Nor does it provide sufficient reimbursement to cover the additional costs of preparing, delivering, and infusing the product to a patient at home.

NHIA believes CMS should maintain coverage of monoclonal antibody products for COVID-19 under the vaccine program until a similar benefit that allows a licensed home infusion pharmacy to provide COVID-19 treatments in the home or in a pharmacy-owned and operated infusion suite at the current payment rates for each site of care. NHIA notes that the broader types of providers eligible under the vaccine program allows home infusion therapy services providers to

work in collaboration with physicians and hospitals to expand their capacity for treating patients diagnosed with COVID-19 and to offer prophylaxis.

NHIA Recommendation:

NHIA requests that CMS continue the current or similar flexibilities to allow home infusion therapy services providers to continue providing this treatment after the end of the public health emergency. NHIA supports maintaining coverage of monoclonal antibody products for COVID-19 under the vaccine benefit or employing a similar benefit that allows a licensed home infusion pharmacy to provide COVID-19 treatments in the home or in a pharmacy-owned and operated infusion suite at the current payment rates for each site of care.

Removal of Selected National Coverage Determinations – NCD 180.2 Enteral and Parenteral Nutritional Therapy

CMS notes that it periodically identifies and eliminates National Coverage Determinations (NCDs) that no longer reflect current, clinically relevant information. CMS proposes to remove the NCD for Enteral and Parenteral Nutritional Therapy (180.2).[2] NHIA appreciates that CMS is recognizing that certain components and language contained within the policy are outdated and is requesting comments regarding its removal. However, NHIA strongly disagrees with removing the Enteral and Parenteral Nutritional Therapy NCD. NCDs play an important role in defining beneficiary coverage for specific products and therapies. The NCDs help to inform all stakeholders of coverage parameters, including Medicare beneficiaries, providers and suppliers, as well as the local Medicare Administrative Contractors (MACs) in their development of Local Coverage Determinations (LCDs). We request that CMS revise the exiting NCD language, to bring it in line with current standards which have evolved significantly since the NCD was published in 1984. NHIA requests that the changes below be made to the existing language regarding parenteral nutrition:

1. Remove all references to "home mix" codes.
2. Update language regarding vascular access device used for parenteral nutrition.
3. Remove the requirement that parenteral nutrition is initiated in the hospital site of care.
4. Remove references to the A/B MAC and case-by-case approval.
5. Remove the requirement for a physician to document the need for an infusion pump.

1. Remove all references to home mix codes

Current language: Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique,

[2] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=242

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the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service.

NHIA believes that home mix of parenteral nutrition (PN) is obsolete, non-compliant, and unsafe and believes these codes should be removed. Parenteral nutrition requires aseptically combining up to 40 or more sterile ingredients. NHIA believes that home mixing of the necessary ingredients to meet the nutrition needs of patients would require dozens of manipulations to combine drugs in the patient home, a non-controlled environment, and should not be allowed for patient safety reasons.

Pharmacies enrolled in the DME program are licensed under section 503A of the Federal Food, Drug and Cosmetic Act. As such, these pharmacies abide by United States Pharmacopeia (USP) standards. USP Chapter <797> addresses pharmaceutical compounding, including aseptic preparation.

Year	Premix Kit B4220	Home Mix Kit B4222	Home Mix %
2018	4,888	27	0.55%
2017	4,796	44	0.91%
2016	4,740	50	1.04%
2015	4,583	49	1.06%
2014	4,498	51	1.12%

The chart above indicates the number of unique beneficiaries that utilized premix versus home mix PN kit codes each year from 2014-2018, based on the publicly available *Medicare Provider Utilization and Payment Data: Referring Durable Medical Equipment, Prosthetics, Orthotics and Supplies*. NHIA believes that the small number of unique beneficiaries that utilized home mix are coding errors.

NHIA Recommendation:

NHIA recommends that CMS remove all references to home mix codes from the Enteral and Parenteral Nutritional Therapy NCD. This will allow the DME MACs to remove all references to home mix from the parenteral nutrition LCD and policy article (PA). This includes removing the following home mix codes:

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HCPCS Code	Description
B4164	Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) - home mix
B4180	Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml = 1 unit) - home mix
B4168	Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - home mix
B4172	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - home mix
B4176	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - home mix
B4178	Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) - home mix
B4216	Parenteral nutrition; additives (vitamins, trace elements, heparin, electrolytes), home mix, per day
B4222	Parenteral nutrition supply kit; home mix, per day

2. Update language regarding vascular access device used for parenteral nutrition

Current Language: Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion.

NHIA believes that the phrase "plugged by the patient" should be replaced with "protected with a new sterile injection cap."

NHIA Recommendation:

NHIA recommends that CMS update the language regarding vascular access device use and maintenance as described above.

3. Removal of requirement that parenteral nutrition is initiated in the hospital site of care

Current Language: Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service.

Many home infusion providers have parenteral nutrition home-start programs. With the proper support, many patients can, and do, safely begin their parenteral nutrition in the home setting at a reduced cost to the insurer. The ability to initiate parenteral nutrition in the home setting allows vulnerable individuals to avoid hospitalization and reduce their exposure to infectious diseases.

NHIA Recommendation:

NHIA requests that CMS permit, but not require, beneficiaries to start parenteral nutritional therapy in the hospital setting.

4. Remove references to the A/B MAC and case-by-case initial and periodic approvals

Current Language: However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than three months by the Medicare Administrative Contractor (A/B MAC (B)) medical consultant or specially trained staff, relying on such medical and other documentation as the A/B MAC (B) may require.

Parenteral nutrition is covered under the prosthetic benefit and billed to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The Enteral and Parenteral Nutritional Therapy NCD has not been updated since before the DMEPOS program was put in place. The DME MACs have processes in place to adjudicate and audit claims for Enteral and Parenteral Nutritional Therapy products.

NHIA Recommendation:

NHIA requests that CMS remove references to the A/B MAC and case-by-case approval process.

5. Remove the requirement for a physician to document the need for an infusion pump

Current Language: If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation

Parenteral nutrition involves administering a large volume of solution, usually two to four liters or more, over 12 to 24 hours at a continuous infusion rate. Many patients opt to infuse their parenteral nutrition during the nighttime hours. Typically, the infusion rate ramps up slowly at the start of the infusion and then back down at the end of the cycle. Large-volume infusion pumps used to administer parenteral nutrition in the home have a programmable ramp feature and other safety features, such as occlusion and anti-free-flow features that are important safety

measures. Since the use of an infusion pump is inherent and ubiquitous with the administration of home parenteral nutrition, NHIA suggests CMS eliminate the requirement for additional documentation beyond the order for parenteral nutrition to support the need for a pump to reduce the administrative burden on physicians and suppliers.

NHIA Recommendation:

NHIA requests that CMS remove the requirement that a physician justify the need for an infusion pump to administer parenteral nutritional therapy to reduce the administrative burden on physicians and suppliers.

Recommendations for Enteral Nutrition

Current Language: However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis.

NHIA notes that the MACs do not have the processes in place to provide prior approval in a timely manner, which causes delays in access for beneficiaries. These delays are not in the interest of Medicare beneficiaries and may lead to detrimental effects on their health. The DME MACs do, however, have processes in place to adjudicate and audit claims for enteral and parenteral nutritional therapy products.

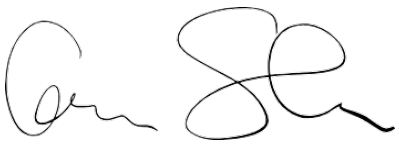
NHIA Recommendation:

NHIA requests that CMS remove the case-by-case approval requirement for enteral nutrition coverage.

In summary, NHIA strongly recommends against removing the Enteral and Parenteral Nutritional Therapy NCD and requests that CMS instead revise the existing NCD language consistent with the above recommendations. In addition, we urge CMS to open the NCD for a transparent public review, including open meetings and comments solicitations.

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

Sincerely,



Connie Sullivan, B.S. Pharm
President and Chief Executive Offic3