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August 20, 2020

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention CMS-1711-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

RE: CMS-1730-P; Medicare and Medicaid Programs; CY2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements (the "Proposed Rule")

Dear Administrator Verma:

OptumRx, UnitedHealth Group's pharmacy care services business, is pleased to respond to the Centers for Medicare & Medicaid Services (CMS) Proposed Rule titled "*Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements.*" Specifically, OptumRx is commenting on Section V of the proposed rule, Home Infusion Therapy, related to policies regarding the permanent home infusion therapy services benefit for CY 2021.

UnitedHealth Group is a mission-driven organization dedicated to helping people live healthier lives and helping our health care system work better for everyone through two distinct business platforms – UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of 325,000 people serves the health care needs of 136 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We not only serve as one of the nation's most progressive health care delivery organizations, we also serve people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 31 states and the District of Columbia.

OptumRx has 28,000 dedicated employees – including more than 7,000 pharmacists and pharmacy technicians – working every day to improve the quality of pharmacy care services, simplify the health care experience, and ensure that the individuals we are privileged to serve have affordable access to the drugs they need. OptumRx helps deliver pharmacy care services to 250,000 patients each day. These services help improve health outcomes for patients and reduce costs in the system.

Optum Infusion Pharmacy, an OptumRx company, is the second largest home infusion pharmacy in the nation with over 50 infusion pharmacy sites. We employ close to 1,000 nurses and provided care to 16,923 Medicare beneficiaries during 2019. At Optum Infusion Pharmacy, our top priority is patient care. Home infusion therapy is our specialty; we offer patients the latest in-home infusion therapy technology and our pharmacists, nurses and other clinical staff are focused on all aspects of service from initial referral through the conclusion of treatment. In caring for the patient, we recognize the importance of the caregiver, the ordering physician and their staff as well as the hospital discharge planner and the managed care company.

Our comprehensive, compassionate care covers a full range of services for home infusion therapy including:

- Personalized referral process – Optum Infusion Pharmacy tailors the process, utilizing the most convenient referral method for the individual referring site which includes hospitals, physician offices, home health agencies and managed care plans.
- Expert insurance verification and processing – Optum Infusion Pharmacy contracts with most managed care plans and we take extreme pride in our reimbursement expertise. We provide quick and accurate verification of a patient's benefits for coverage and supply patient balance information clearly and concisely upfront.
- Coordination of appropriate nursing services – Optum Infusion Pharmacy coordinates nursing services with employed or agency nurses having the necessary education as well as any clinical skills required to ensure the safe completion of therapy.
- Convenient delivery of medication and all necessary supplies - All medications and supplies, as well as concise storage instructions, are delivered directly to the patient by Optum Infusion Pharmacy.
- Customized patient education materials - Our educational materials are easy-to-read and tailored to each patient based on the specific drug and delivery mode. Additional useful materials on safety, nutrition, falls, emergency preparedness and other compliance information are included.
- Clinical pharmacy monitoring - Optum Infusion Pharmacy monitors all clinical aspects of the patient's therapy, including lab values, screening for drug interactions, dosage and frequency and compliance. Direct and ongoing communication with the patient and physician throughout care ensuring that changes or adjustments to treatment are made as needed.

### **OptumRx Recommendations**

A summary of our recommendations is provided here and articulated in greater detail below. OptumRx requests that CMS:

- 1) Continue to allow home infusion therapy services providers to bill for infusion services that were provided within 30 days of the drug.
- 2) Revise the existing definition of infusion drug administration calendar day to allow for reimbursement of home infusion professional services, irrespective of whether a skilled professional is in the individual's home. Allow home infusion providers to utilize telehealth when providing pharmacist and nursing professional services in accordance with the plan of care authorized by the physician.
- 3) Include Xembify<sup>®</sup> and Cutaquig<sup>®</sup> in payment category two in the final rule.
- 4) Permit home infusion therapy suppliers to bill all 12 A/B MACs from a single location/National Provider Identifier (NPI) without requiring them to maintain a physical presence in the state or jurisdiction.

### Home Infusion Therapy Services Billing

OptumRx is concerned about the apparent narrowing of the situations in which home infusion therapy services may be billed. In the Proposed Rule, CMS states that payment to a qualified home infusion therapy supplier may occur "only for the date on which professional services were furnished to administer" infusion drugs to an individual and that "it is necessary for the qualified home infusion therapy supplier to be in the patient's home on occasions when the drug is being administered."<sup>1</sup> OptumRx is concerned that CMS is restricting access to home infusion therapy services without justification.

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<sup>1</sup> 85 Fed. Reg. 39434 (June 30, 2020).



Under the temporary transitional benefit, home infusion therapy services providers were permitted to bill for services if the appropriate drug associated with the visit was billed with the visit or no more than 30-days prior to the visit. CMS' more restrictive language in the Proposed Rule prohibits a home infusion therapy services supplier from billing for essential services provided in accordance with the plan of care that do not occur on days when an infusion drug is being administered. For example, a home infusion nurse might respond to a patient call after hours to perform a visit to assess an IV catheter that has become occluded or dislodged. Under this draft rule, a visit performed to assess the catheter and report to the physician would not be billable. Additionally, providers should also not be precluded from performing education and training that facilitates the transition of care between the hospital and the home, as is often done when patients are discharged in the evening, but the next dose of medication does not occur until the following day.

CMS provides no justification for the much more restrictive billing rule under the permanent benefit and OptumRx is concerned that this change will reduce access to home infusion therapy for vulnerable Medicare beneficiaries. The unintended consequence of equating the home infusion therapy services benefit to drug administration misses the point of home infusion all together, which is to provide comprehensive support and avoid the unnecessary expense and burden associated with emergency department visits and hospitalization when the issue can be resolved at home by the clinician.

**OptumRx requests that CMS continue to allow home infusion therapy services providers to bill for services if the appropriate drug associated with the visit was billed with the visit or no more than 30-days prior to the visit. If CMS wishes to change this rule, OptumRx asks that CMS provide its rationale and justification for such a change.**

#### Access to Home Infusion Therapy Services

OptumRx has long expressed concern that CMS's definition of "infusion drug administration calendar day" would have the effect of reducing access to home infusion therapy services for vulnerable Medicare beneficiaries. OptumRx believes that the data bears this out. Data obtained by the National Home Infusion Association (NHIA) via a Freedom of Information Act request shows that Medicare payments for home infusion therapy services under the transitional benefit for the first quarter of 2019 were less than \$1 million. In addition, claims data obtained by NHIA through a third party shows that Medicare paid less than \$4 million for home infusion therapy services for all of calendar year 2019. This amount is a tiny fraction of the \$60 million that was projected as an annual amount for home infusion therapy services and is evidence that access to the full range of home infusion therapy services is restricted.

At a time when commercial payers are incentivizing the home site of care for infused drugs, Medicare policy remains fractured, with large coverage gaps that disincentivize the home site of care by limiting the range of services and under-paying suppliers. This is particularly troubling during the current COVID-19 pandemic, when it is more critical than ever that vulnerable Medicare beneficiaries have access to safe at-home treatments and hospitals are able to focus on serving COVID-19 patients. The current policy that requires a nurse or other skilled professional to be physically present in the home in order for services to be reimbursed puts these patients and their caregivers at risk, despite the fact that much of the support and monitoring for these patients could be conducted remotely.

Section 1861(iii)(2) of the Social Security Act includes remote monitoring among the items and services that are included in the definition of "home infusion therapy." Despite this clear intent of Congress to provide for payment of remote monitoring services, CMS has restricted payment to days on which the nurse or skilled professional is physically present in the home. This is



particularly problematic in the context of the current public health emergency, during which CMS has provided for payment of telehealth services for many other services including mental health services, physician services, end-stage renal disease and home health services. Indeed, in the proposed rule, CMS provides detailed examples of other categories of services including training and education, patient assessment and evaluation, and medication and disease management and education, but is silent on any details related to remote monitoring. OptumRx encourages CMS to take advantage of the opportunity to protect vulnerable Medicare beneficiaries from the risks of COVID-19 when it has specific legislative authority to do so.

**OptumRx strongly encourages CMS to revise the existing definition of “infusion drug administration calendar day” to allow for reimbursement of home infusion professional services, irrespective of whether a skilled professional is in the individual’s home. We also request that CMS allow home infusion providers to bill services codes G0068, G0069, and G0070 for pharmacist and nursing professional services provided remotely in accordance with the plan of care authorized by the physician. Making these changes will help ensure that Medicare beneficiaries have adequate access to this important benefit and reduce the risk of exposure to COVID-19 for Medicare beneficiaries, their caregivers, and health professionals.**

#### Payment Categories for Xembify® and Cutaquig®

Section 1834(u)(7)(C) of the Social Security Act states that the Secretary of the Department of Health and Human Services (HHS) is required to assign the appropriate payment category (payment category one (1), two (2) or three (3)) to drugs that are covered under the Durable Medical Equipment (DME) local coverage determination (LCD) for external infusion pumps and billed under HCPCS codes J7799 and J7999. In the Proposed Rule, CMS states that subsequent drugs added to the DME LCD for external infusion pumps under HCPCS codes J7799 and J7999 would be grouped into the appropriate payment category by the DME Medicare Administrative Carriers (MACs). CMS notes that payment category 1 would include any subsequent additions to intravenous infusion drugs, payment category 2 would include any subsequent additions to subcutaneous infusion drugs, and payment category 3 would include any subsequent additions to intravenous chemotherapy or other highly complex drug or biologic infusions.<sup>2</sup>

OptumRx notes that Xembify® J1558 (INJECTION, IMMUNE GLOBULIN (XEMBIFY), 100 MG) was added to the External Infusion Pump LCD effective May 31, 2020 and should be reflected as a category 2 drug in Table 12 of the Proposed Rule. In addition, on July 23, 2020, the DME MACs released the final External Infusion Pump LCD, which adds coverage of Cutaquig® effective September 6, 2020. Cutaquig® also should be listed as a category 2 drug in future rule making.

**OptumRx requests that CMS include Xembify® and Cutaquig® in payment category 2 in the final rule.**

#### Enrollment Issues

CMS proposes to require that home infusion therapy suppliers complete and submit the form CMS-855B Medicare enrollment form. In addition, CMS previously has stated that home infusion therapy suppliers will be required to enroll in each of 12 Medicare A/B MACs in order to bill for home infusion therapy services in those areas. OptumRx has concerns that this enrollment requirement is unduly burdensome. In addition, home infusion therapy professional services are primarily pharmacy-based and currently do not require the provider to be in the same physical

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<sup>2</sup> *Id.* at 39437.



state as the patient. OptumRx is concerned that some A/B MACs will require providers to have a physical presence in their jurisdiction or state, which would dramatically reduce the number of providers available to Medicare beneficiaries, especially in rural areas.

**OptumRx requests that home infusion therapy suppliers be permitted to bill all 12 A/B MACs from a single location/National Provider Identifier (NPI), as state laws allow, without requiring them to maintain a physical presence in the state or jurisdiction.**

OptumRx appreciates the opportunity to provide comments on these Section V of the Proposed Rule, Home Infusion Therapy. We welcome the opportunity to continue working with CMS to improve the Medicare home infusion therapy services benefit for Medicare beneficiaries.

Sincerely,

A handwritten signature in blue ink that reads "John Prince".

John M Prince  
Chief Executive Officer, OptumRx, Inc