



National Home Infusion Association

Providing solutions for the infusion therapy community

May 16, 2018

Ms. Elan Green
Chief, Medical Benefits & Reimbursement
Division at the Defense Health Agency
16401 Centretech Parkway
Aurora, CO 80011

Dear Ms. Green:

The National Home Infusion Association (NHIA), represents the interests of providers and suppliers of infusion and specialized pharmacy products and services to home-based patients. We are writing to make you aware that HealthNet, one of the two TRICARE Managed Care contractors, is incorrectly applying a Medicare Part B payment policy for certain infused drugs based on an incorrect interpretation of changes in the *Social Security Act* that was enacted as part of Section 5004 of the *21st Century Cures Act* (Public Law: 114—258).

Section 5004 of the *21st Century Cures Act* changed the payment structure for infusion drugs under the Medicare Part B Durable Medical Equipment (DME) benefit from an Average Wholesale Price (AWP) metric to an Average Sales Price (ASP) payment methodology for Part B DME drugs only. Unfortunately, we have information that indicates Healthnet is incorrectly applying the ASP payment methodology well beyond congressional intent by extending the ASP reimbursement methodology to drugs that are currently provided in the Medicare Part D program.

Section 5004 is **only** intended to alter drug pricing for home infusion drugs that are part of the **Medicare Part B DME** program. Section 5004 of the *21st Century Cures Act* reads as follows (emphasis added):

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

*(a) Treatment of Infusion Drugs **Furnished Through Durable Medical Equipment.** -- Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—*

(1) in subparagraph (C), by inserting ``(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)'' after ``2005''; and

(2) in subparagraph (D)—

(A) by striking ``infusion drugs'' and inserting ``infusion drugs or biologicals'' each place it appears; and

(B) in clause (i)—

(i) by striking ``2004'' and inserting ``2004, and before January 1, 2017''; and

(ii) by striking "for such drug".

(b) Noninclusion of DME Infusion Drugs Under DME Competitive Acquisition Programs. —

(1) In general. -- Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is amended—

(A) by striking "and excluding" and inserting " , excluding"; and
(B) by inserting before the period at the end the following: " , and excluding drugs and biologics described in section 1842(o)(1)(D)".

(2) Conforming amendment. -- Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking "2007" and inserting "2007, and before the date of the enactment of the 21st Century Cures Act."

This section of the law only applies to home infusion drugs that are furnished through DME as part of the Medicare Part B program. There is a long history of congressional intent regarding this provision and its applicability to a limited set of drugs. There are only 39 drugs that are covered in the Medicare Part B DME program. These drugs are listed in the "Medicare Local Coverage Determination (LCD): External Infusion Pumps (L33794)." The drugs are as follows:

J0133 INJECTION, ACYCLOVIR, 5 MG
J0285 INJECTION, AMPHOTERICIN B, 50 MG
J0287 INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG
J0288 INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG
J0289 INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG
J0895 INJECTION, DEFEROXAMINE MESYLATE, 500 MG
J1170 INJECTION, HYDROMORPHONE, UP TO 4 MG
J1250 INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
J1265 INJECTION, DOPAMINE HCL, 40 MG
J1325 INJECTION, EPOPROSTENOL, 0.5 MG
J1455 INJECTION, FOSCARNET SODIUM, PER 1000 MG
J1457 INJECTION, GALLIUM NITRATE, 1 MG
J1555 INJECTION, IMMUNE GLOBULIN (CUVITRU), 100 MG
J1559 INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG
J1561 INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1562 INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG
J1569 INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G., LIQUID), 500 MG
J1570 INJECTION, GANCICLOVIR SODIUM, 500 MG
J1575 INJECTION, IMMUNE GLOBULIN/HYALURONIDASE, (HYQVIA), 100 MG IMMUNEGLOBULIN
J1817 INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS
J2175 INJECTION, MEPERIDINE HYDROCHLORIDE, PER 100 MG
J2260 INJECTION, MILRINONE LACTATE, 5 MG
J2270 INJECTION, MORPHINE SULFATE, UP TO 10 MG

J2274 INJECTION, MORPHINE SULFATE, PRESERVATIVE-FREE FOR EPIDURAL OR INTRATHECAL USE, 10 MG
J2278 INJECTION, ZICONOTIDE, 1 MICROGRAM
J3010 INJECTION, FENTANYL CITRATE, 0.1 MG
J3285 INJECTION, TREPROSTINIL, 1 MG
J7340 CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION, 100 ML
J7799 NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME
J7999 COMPOUNDED DRUG, NOT OTHERWISE CLASSIFIED
J9000 INJECTION, DOXORUBICIN HYDROCHLORIDE, 10 MG
J9039 INJECTION, BLINATUMOMAB, 1 MICROGRAM
J9040 INJECTION, BLEOMYCIN SULFATE, 15 UNITS
J9065 INJECTION, CLADRIBINE, PER 1 MG
J9100 INJECTION, CYTARABINE, 100 MG
J9190 INJECTION, FLUOROURACIL, 500 MG
J9200 INJECTION, FLOXURIDINE, 500 MG
J9360 INJECTION, VINBLASTINE SULFATE, 1 MG
J9370 VINCRISTINE SULFATE, 1 MG

Section 5004 does not extend past this specific set of home infusion drugs because other home infusion drugs are covered via the Medicare Part D benefit. Furthermore, ASP pricing should not be extended to the drugs listed above if they are administered without the use of a durable infusion pump.

In contrast to the HealthNet's incorrect determination, we understand that Humana is properly applying the policy. More specifically, Humana is using the ASP payment methodology *only* for Medicare Part B DME covered infused drugs. Conversely, HealthNet is inappropriately applying the ASP pricing methodology for *all* infused drugs. NHIA requests that you give guidance to Healthnet regarding their statutorily incorrect review of drug pricing methodology for home infusion drugs due to enactment of Section 5004, "Reducing Overpayments of Infusion Drugs" of the *21st Century Cures Act*. TRICARE and its vendors should only apply the ASP plus six percent pricing methodology to Medicare Part B DME covered infused drugs. The TRICARE Reimbursement Manual Chapter 3 Section 6.2.2.1.3 (rev. August 2017) states:

2.2.1.3 Effective January 1, 2017, drugs infused through Durable Medical Equipment (DME) shall be priced at ASP plus 6%, in accordance with Section 5004 of the 21st Century Cures Act, and TRICARE's requirement at 10 USC Section 1079 to reimburse like Medicare, where practicable.

Based on the guidance provided in the "TRICARE Reimbursement Manual," home infused drugs, other than those listed in the LCD for external infusion pumps, should not be affected by the new Medicare law. These other home infusion drugs should not be reimbursed at ASP plus six percent, but rather at AWP minus five percent.

Our nation's service members, retirees, and their families, deserve consistent coverage policy that affords them the opportunity to receive infused medications in the comfort of their homes. The home is a cost effective, safe, clinically appropriate site of care and often the preferred choice of patients. While Humana, by example, has correctly understood and implemented the change, HeathNet has not, and its incorrect reimbursement methodology will harm veterans' access and potentially remove a site of care

from the TRICARE program for infusions. This will only serve to increase the cost of care in TRICARE as a whole. We welcome and request the opportunity to meet with you to discuss this issue.

NHIA thanks you for your attention to this matter. Please feel free to contact NHIA's Vice President of Health Information Policy Bill Noyes at Bill.Noyes@nhia.org or 603-736-0308 should you have any questions.

Sincerely,



Tyler J. Wilson
President and CEO
The National Home Infusion Association

CC: Kenneth Canestrini, Acting Director, TRICARE Health Plan, Defense Health Agency

¹ <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD>