Medlearn Matters
Information for Medicare Providers

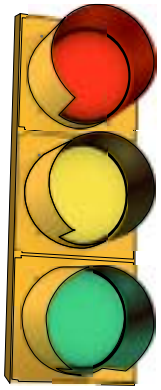
Related Change Request (CR) #: 2984
Medlearn Matters Number: MM2984
Related CR Release Date: March 5, 2004
Related CR Transmittal #: 8
Effective Date: April 1, 2004
Implementation Date: April 5, 2004

Frequency Limitations for Darbepoetin Alfa (trade name Aranesp) for Treatment of Anemia in End Stage Renal Disease (ESRD) Patients on Dialysis

Provider Types Affected

Renal Dialysis Facilities.

Provider Action Needed



STOP – Impact to You

Medicare is instituting new frequency limitations for treatment of ESRD patients on dialysis with Darbepoetin Alfa (trade name Aranesp).

CAUTION – What You Need to Know

Be aware of these frequency limitations to assure correct and timely payment for services supplied to Medicare patients.

GO – What You Need to Do

Make sure you understand the changes effective for services provided on and after April 1, 2004 for the frequency limitations on Darbepoetin Alfa for ESRD.

Background

Section 1881(b) (11) (B) of the Social Security Act states that payment will be provided for erythropoietin when a patient diagnosis is ESRD. Darbepoetin Alfa, a new erythropoietin-like product, differs from Epoetin Alfa by the addition of two carbohydrate chains, which lengthens the biologic half-life. This change affects how often the biological can be administered and results in a decreased dosing schedule for Darbepoetin Alfa by comparison to Epoetin Alfa.

Additional Information

This notice establishes frequency limitations for darbepoetin alfa, and also reiterates the frequency limitations for Epoetin Alfa (trade name EPO) will remain the same. You can refer back to CR2963 for the payment guidelines on Darbepoetin Alfa (trade name Aranesp).

That CR may be found at:

http://www.cms.hhs.gov/manuals/pm_trans/R39OTN.pdf

Please note that this notice does not apply to physicians' payments for Aranesp or EPO; those payments are established in the Drug Payment Limits Pricing File, set by the Medicare Prescription Drug, Modernization, and Improvement Act of 2003.

According to its FDA-approved labeling, Darbepoetin Alfa is to be given once a week, up to a maximum of five times for a calendar month (30/31 days). Coverage rules for Darbepoetin Alfa are the same as Epoetin Alfa for ESRD-related anemia.

To view the actual change request related to this article (CR2984), go to:

http://www.cms.hhs.gov/manuals/pm_trans/R8BP.pdf