



A CMS Program Safeguard Contractor

Budesonide (Pulmicort) – Coverage and Coding

Pulmicort Respules (budesonide) (J7626) is the only FDA-approved corticosteroid inhalation solution. Utilization guidelines for budesonide were included in the revised Nebulizers LCD which was effective for claims with dates of service on or after July 1, 2007. Those guidelines specified a maximum of 62 units of service per month – 2 units of service per day.

Pulmicort Respules is available in unit dose vials containing 0.25 mg, 0.5 mg, and 1.0 mg of budesonide. The unit of service for code J7626 is “up to 0.5 mg”. Therefore, the following guidelines apply to billing unit dose vials of budesonide:

- 0.25 mg vial = 1 unit of service
- 0.5 mg vial = 1 unit of service
- 1.0 mg vial = 2 units of service

According to the package insert, the highest recommended dose of budesonide is 1 mg per day administered as either a single daily dose or as 0.5 mg twice daily. There is no medical advantage to administering budesonide as 0.25 mg four times per day. There is also no proven medical benefit to administering budesonide in doses greater than 1 mg per day. Therefore, coverage of FDA-approved unit dose formulations of budesonide (J7626) is limited to 2 units of service per day.

TrustSolutions, the Jurisdiction C DME PSC, is focusing review activities on suppliers billing excess quantities of budesonide (J7626).

Compounded formulations of budesonide – unit dose form (J7627) and concentrated form (J7634) – are denied as not medically necessary.