

DME MAC Jurisdiction A

Budesonide (J7626) - Coding and Coverage ([DRU](#))

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A recent review of claims for the inhalation medication, budesonide, has identified problems with the coding and coverage of this drug.

Coding Issues

The descriptor for HCPCS code J7626 reads:

J7626 - Budesonide, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, up to 0.5mg

Budesonide is supplied by the manufacturer as Pulmicort Respules® in 0.25, 0.5 and 1.0 mg unit dose vials. The HCPCS code descriptor indicates one unit of service (UOS) = up to 0.5 mg. Therefore, for the 0.25 mg or 0.5 mg unit dose forms, one UOS is billed for each vial dispensed. For the 1.0 mg unit dose form, one vial = two UOS.

When billing code J7626, suppliers should use the following examples:

Example 1: Dispensing 0.5 mg vials

Order is for budesonide 0.5 mg vials, administer 0.5 mg BID
 $0.5 \text{ mg} \times 2\text{x/day} = 1 \text{ mg/day} \times 31 \text{ days} = 31 \text{ mg/month}$
 $1 \text{ vial} \times 2\text{x/day} = 2 \text{ vials/day} \times 31 \text{ days} = 62 \text{ UOS/ month}$
Claim filed for 62 UOS of code J7626

Example 2: Dispensing 0.25 mg vials

Order is for budesonide 0.25 mg vials, administer 0.25 mg BID
 $0.25 \text{ mg} \times 2\text{x/day} = 0.5 \text{ mg/day} \times 31 \text{ days} = 15.5 \text{ mg/month}$
 $1 \text{ vial} \times 2\text{x/day} = 2 \text{ vials/day} \times 31 \text{ days} = 62 \text{ UOS/ month}$
Claim filed for 62 UOS of code J7626

Example 3: Dispensing 0.25 mg vials

Order is for budesonide 0.25 mg vials, administer 0.25 mg TID
 $0.25 \text{ mg} \times 3\text{x/day} = 0.75 \text{ mg/day} \times 31 \text{ days} = 23.25 \text{ mg}$
 $1 \text{ vial} \times 3\text{x/day} = 3 \text{ vials/day} \times 31 \text{ days} = 93 \text{ UOS/ month}$
Claim filed for 93 UOS of code J7626

Coverage Issues

Budesonide is commonly provided as Pulmicort Respules® (AstraZeneca) which has an FDA indication for the maintenance and treatment of asthma and as a prophylactic therapy in children 12 months to 8 years old. Use for chronic obstructive pulmonary disease (COPD) is considered “off-label” use and therefore subject to the Centers for Medicare & Medicaid Services (CMS) policy on unlabeled use of medications found in the *Benefits Policy Manual*, Internet Only Manual Pub. 100-2, Chapter 15, Section 50.4.2.

There is nothing in the medical literature supporting the use of budesonide at a frequency greater than twice per day (regardless of whether 0.5 mg or 0.25 mg dose is used) or a cumulative dose greater than 1 mg/day. Therefore, according to the local coverage determination (LCD) for Nebulizers, the maximum allowed amount is 62 units of service per month. Billing for quantities greater than 62 UOS per month will be denied as not medically necessary.

In example #3, even though the total mg administered (23.25 mg/mo) is within the policy guidelines (31 mg/mo), the 93 units of service exceeds the guidelines. If 0.75 per day is ordered, there is no medical necessity for three times per day administration. Administration of one 0.5 mg dose and one 0.25 dose per day would be appropriate. The excess units of service will be denied as not medically necessary.

Suppliers should refer to the Nebulizers LCD for additional guidance on the coverage, coding and documentation requirements.