

| PA Criteria | Criteria Details | | | | | | |
|---|--|---|-------------|----------------------------|-------|--|---|
| Covered Uses (FDA approved indication) | Vyalev injection is a combination of prodrugs foscarnidopa and foslevodopa and is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD). | | | | | | |
| Exclusion Criteria | None. | | | | | | |
| Required Medical Information | <p>Medical records to support the request, including documentation of the following:</p> <ol style="list-style-type: none"> 1. Patient has levodopa-responsive advanced PD with clearly defined "on" periods; 2. Patient is receiving optimal carbidopa/levodopa therapy; 3. Patient has persistent motor fluctuations despite therapy with the following: levodopa or levodopa-carbidopa AND one other class of anti-Parkinson's therapy including dopamine agonists (e.g., pramipexole, ropinirole), MAO-B inhibitors (e.g., rasagiline, selegiline), COMT inhibitors (e.g., entacapone). | | | | | | |
| Other Criteria | Must follow Local Coverage Determination (LCD) L33374 External Infusion Pumps. LCD - External Infusion Pumps (L33794) | | | | | | |
| Age Restriction | Patient is at least 18 years of age. | | | | | | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a neurologist. | | | | | | |
| Coverage Duration | <p>Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.</p> <p>For reauthorization: Documentation of positive clinical response to Vyalev therapy.</p> | | | | | | |
| Other Criteria/Information | <p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J7356</td> <td>Vyalev (foscarnidopa 0.25 mg / foslevodopa 5 mg)</td> <td>Billing unit: 5.25 mg 120 mg/2,400 mg per 10 mL SDV</td> </tr> </tbody> </table> | HCPCS | Description | Billing Units/How Supplied | J7356 | Vyalev (foscarnidopa 0.25 mg / foslevodopa 5 mg) | Billing unit: 5.25 mg 120 mg/2,400 mg per 10 mL SDV |
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| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|----------|--------------|-------------|---|----------------|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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