TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

VORAXAZE® *(glucarpidase)* injection, for IV use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>VORAXAZE is a carboxypeptidase indicated to reduce toxic plasma methotrexate concentration.</td></tr>
<tr><td>Covered Uses
(FDA approved indication)</td><td>VORAXAZE is a carboxypeptidase indicated to reduce toxic plasma methotrexate concentration (greater than one micromole per liter) in adult and pediatric patients with delayed methotrexate clearance (plasma methotrexate concentrations greater than two standard deviations of the mean methotrexate excretion curve specific for the dose of methotrexate administered) due to impaired renal function.

VORAXAZE is NOT recommended for use in patients who exhibit the expected clearance and expected plasma methotrexate concentration.</td></tr>
<tr><td>Dosing and Administration</td><td>
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<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>MTX Toxicity</td><td>50 units/kg as a single IV injection over five minutes.

Flush IV line before and after administration.

For the first 48 hours after the dose of VORAXAZE, administer the same leucovorin dose given prior to VORAXAZE. Administer leucovorin at least two hours before or two hours after the dose of VORAXAZE.

Beyond 48 hours after the dose of VORAXAZE, administer leucovorin based on the measured MTX concentration. Continue leucovorin until the MTX concentration has been maintained below the leucovorin treatment threshold for a minimum of three days.</td><td>50 units/kg (single dose)</td></tr>
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<tr><td>Billing and Coding Information</td><td>
<table>
<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>50633-210-11</td><td>50633-0210-11</td></tr>
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<table>
<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J3590</td><td>Unclassified biologics</td></tr>
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<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96374</td><td>Therapeutic/Prophylactic/Diagnostic injection, IV push</td></tr>
<tr><td>96375</td><td>Therapeutic/Prophylactic/Diagnostic IV injection, new drug add-on</td></tr>
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</td></tr>
<tr><td>Product Availability</td><td>Single-dose vial: 1000 units as a lyophilized powder for reconstitution</td></tr>
<tr><td>Contraindications</td><td>None.</td></tr>
<tr><td>Recommended Medical Monitoring</td><td>VORAXAZE has been associated with:
• Serious hypersensitivity reactions

Measure Methotrexate concentrations within 48 hours following VORAXAZE administration using a chromatographic method; immunoassays are unreliable for samples collected within 48 hours following VORAXAZE administration.</td></tr>
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Approval Criteria	a. Physician administered IV injection; in-office or HOPD i. Cannot be self-administered b. Methotrexate Toxicity (must meet all): i. Delayed methotrexate clearance due to renal impairment (i.e. creatinine clearance is 60 mL/min or less) ii. Plasma concentration of methotrexate is > one micromole per liter prior to the first dose of glucarpidase (patients who received a second dose failed to achieve efficacy) iii. Administered with IV hydration, urinary alkalinization, and leucovorin therapy (not given within two hours before or after glucarpidase). iv. Request meets one of the following: a. Dose does not exceed 50 units/kg (single-dose limit) b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)
Age Restriction	None.
Coverage Duration	Approved per needed single-dose. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/19/26	1/19/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26