

PROVIDER QUICK POINTS

PROVIDER INFORMATION



May 13, 2020

Medical Drug Update for New to Market Valoctocogene Roxaparvovec (Valrox)

As stewards of healthcare expenditures for our subscribers, we are charged with ensuring our subscribers receive safe, appropriate, and highest quality care while also managing overall costs. As new medical drugs and/or drug indications are approved by the Food and Drug Administration (FDA) for use in the United States, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) carefully examines the scientific evidence and outcomes of the drug treatments. Medical drugs are generally administered by infusion or injection by a healthcare professional and process under a subscriber's medical benefit. During the review process, Blue Cross may decide a new to market drug requires further evaluation to determine appropriate coverage or utilization management policies under the medical benefit.

Medical Drug Evaluation Process

As new to market medical drugs are evaluated, Blue Cross's **Medical Drug Evaluation Process** involves clinical review of recent FDA-approved medical drugs or medical drug indications within 6 months of FDA approval. Blue Cross's Medical Policy Committee carefully examines the scientific evidence and outcomes for each medical drug treatment under consideration. The clinical review includes evaluation of published data and evidence supporting the safety, effectiveness, and the effect of the drug on health outcomes. The Medical Policy Committee's goal is to find the right balance between making new treatments available and guarding against unsafe or unproven approaches.

While new medical drugs and/or drug indications are under clinical review, the treatment is considered experimental- investigative until the evaluation process has been completed and a determination made if the treatment should be a covered service under the medical benefit. Covered services are determined in accordance with Blue Cross' policies in effect at the time treatment is rendered. Claims submitted while a drug is under review are subject to retrospective review and may be denied.

On February 20, 2020 the FDA granted priority review designation for Valoctocogene Roxaparvovec (Valrox). The Prescription Drug User Fee Act (PDUFA) action date is August 21, 2020. **Upon FDA approval, Valrox will be added to the Blue Cross [Medical Drug Evaluation Process List](#).** While the drug is under clinical review, the treatment is considered experimental/investigative until the evaluation process is completed and a determination is made if the treatment should be a covered service under the medical benefit.

Members Impacted

Subscribers with coverage through Commercial health plans (excluding Federal Employee Program (FEP) which has separate requirements).

Notes:

- Providers are encouraged to review the Medical Drug Evaluation Process List periodically for updates.
- Medical drugs do not include drugs that process under the pharmacy benefit, such as self-administered drugs or oral pills which do not need to be given by a health care provider or under their supervision.

QP43-20 Distribution: Available online at: <https://www.bluecrossmn.com/healthy/public/personal/home/providers/forms-and-publications>

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L264R03 (12/13)

- The requirement of Committee Review is a precondition of Blue Cross coverage and applies in addition to all other conditions and terms stated in Blue Cross contracts. For additional information on the Medical Drug Evaluation Process, see **Medical Policy II-174: New FDA-Approved Medical Drugs or Medical Drug Indications**. To access Blue Cross medical policies:
 - Go to providers.bluecrossmn.com
 - Under Tools and Resources, select “Medical Policy”, then acknowledge the Acceptance statement
 - Select the “+” (plus) sign next to Medical and Behavioral Health Policies

Questions?

If you have questions, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.