

IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT202495 JUNE 25, 2024

IHCP adds coverage for Hemgenix treatment

On April 1, 2023, the Centers for Medicare & Medicaid Services (CMS) added a new Healthcare Common Procedure Coding System (HCPCS) code J1411 – *Injection, etranacogene dezaparvovec-drlb, per therapeutic dose* for Hemgenix injections for treatment of hemophilia B. At that time, the Indiana Office of Medicaid Policy and Planning (OMPP) recommended that the Indiana Health Coverage Programs (IHCP) not add coverage for this code.

Effective immediately, for dates of service (DOS) on and after **June 1, 2023**, the IHCP will now reimburse IHCP-enrolled providers for etranacogene dezaparvovec-drlb (Hemgenix) treatment provided to members age 18 years and older. This coverage applies to both the medical benefit (when billed with HCPCS code J1411) and the pharmacy benefit.

IHCP coverage of Hemgenix requires prior authorization (PA). This agent may be considered medically necessary when the member meets **all** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of congenital Factor IX deficiency (hemophilia B)
- Has one of the following (documentation required):
 - Currently requires Factor IX prophylaxis therapy
 - Currently has, or has history of, life-threatening hemorrhage
 - Has experienced two or more spontaneous bleeding episodes that required hospitalization or intervention to prevent permanent damage or disability
- Has medication prescribed by, or in consultation with, a hematologist qualified to administer etranacogene dezaparvovec-drlb from a qualified treatment center
- Has a recently obtained adeno-associated vector serotype 5 (AAV-5) neutralizing antibody titer less than or equal to 1:700
- Has negative test results for **all** the following (documentation must be provided):
 - Factor IX inhibitor titer
 - Hepatitis B and C
 - Human immunodeficiency virus (HIV)
 - Liver fibrosis score greater than or equal to 3
- Has not been diagnosed with end-stage renal disease
- Has not received a prior gene therapy treatment

The National Drug Code (NDC) is required when billing HCPCS code J1411.

When Hemgenix treatment is provided in an inpatient setting, separate reimbursement is available outside the inpatient diagnosis-related group (DRG) when HCPCS J1411 is submitted separately on a professional claim.

Hemgenix is carved out from managed care, which means that claims and PA are processed through the fee-for-service (FFS) delivery system for all members. Under the medical benefit, for both managed care and FFS members, PA for procedure code J1411 should be submitted to the FFS nonpharmacy prior authorization and utilization management (PA-UM) contractor, Acentra Health, and claims (professional and institutional-outpatient) should be submitted to the FFS nonpharmacy claim-processing contractor, Gainwell Technologies. Pharmacy PA and claims for both managed care and FFS members should be submitted to the FFS pharmacy benefit manager, Optum Rx.

Table 1 – Newly covered code for hemophilia B gene therapy (Hemgenix), effective for DOS on or after June 1, 2023

Procedure code	Description	Program coverage	PA required	NDC required	Reimbursement notes
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	Covered under Traditional Medicaid and other IHCP programs that include full Indiana Medicaid State Plan benefits; the service may not be covered under IHCP plans with limited benefits	Yes	Yes	Max Fee: \$3,675,000 Limited to one unit per member per lifetime Restricted to members age 18 years and older Linked to revenue code 636 Carved out of managed care and separately reimbursed for inpatient settings

This new coverage information will be reflected in the next regular update to the Professional Fee Schedule and Outpatient Fee Schedule, accessible from the [IHCP Fee Schedules](#) page at in.gov/medicaid/providers.

Updates will also be made to the following code tables, accessible from the [Code Sets](#) page at in.gov/medicaid/providers:

- *Physician-Administered Drugs Carved Out of Managed Care and Reimbursable Outside the Inpatient Diagnosis-Related Group (DRG)*
- *Procedure Codes That Require National Drug Codes*
- *Revenue Codes With Special Procedure Code Linkages*

Questions about PA specific to Hemgenix procedure code J1411 for all IHCP members should be directed to Acentra Health Customer Service at 866-725-9991. Questions about professional or institutional billing and reimbursement for procedure code J1411 for all IHCP members should be directed to Gainwell Technologies at 800-457-4584.

Questions about PA, billing and reimbursement through the pharmacy benefit should be directed to Optum Rx Clinical and Technical Help Desk at 855-577-6317.

Individual managed care entities (MCEs) establish and publish PA, billing and reimbursement criteria within the managed care delivery system. Questions about managed care billing and PA for procedures **other than, but related to, procedure code J1411 (Hemgenix)** should be directed to the MCE with which the member is enrolled.

QUESTIONS?

If you have questions about this publication, please contact Customer Assistance at 800-457-4584.

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