
Gene Therapy Billing Policy

Policy Statement

To create a billing/payment policy for Neighborhood Health Plan of Rhode Island (Neighborhood) regarding gene therapy products.

Scope

This policy applies to:

- ☒ **Medicaid** *excluding Extended Family Planning (EFP)*
- ☒ **Commercial**
- ☒ **Dual CONNECT (Coordination only D-SNP)**
- ☒ **INTEGRITY for Duals (Fully Integrated D-SNP)**

Prerequisites

All services must be medically necessary to qualify for reimbursement. Neighborhood may use the following criteria to determine medical necessity:

- National Coverage Determination (NCD)
- Local Coverage Determination (LCD)
- Industry accepted criteria such as Interqual
- Rhode Island Executive Office of Health and Human Services (EOHHS) recommendations
- Clinical Medical Policies (CMP)

It is the provider's responsibility to verify eligibility, coverage and authorization criteria prior to rendering services.

For more information please refer to:

- Neighborhood's plan specific [Pharmacy Prior Authorization Criteria and Clinical Medical Policies](#).

Please contact Provider Services at 1-800-963-1001 for questions related to this policy.

Reimbursement Requirements

Neighborhood Health Plan of Rhode Island will provide payment of gene therapy products when administered within the following guidelines.

1. For gene therapies that require an authorization, additional documentation is required to be submitted to the pharmacy department for review prior to administration. The clinical medical policies can be found online at: <https://www.nhpri.org/providers/provider->

[resources/pharmacy/criteria-and-clinical-medical-policies/](#) Failure to submit accurate HCPCS codes, units, or additional clinical documentation may result in non-payment.

2. The State of Rhode Island is participating in the [Centers for Medicare & Medicaid Services \(CMS\) Cell and Gene Therapy \(CGT\) Access Model](#). Information is available on the [State Medicaid Agency's website](#) and the State's clinical criteria for the drugs included in the model (Casgevy, Lyfgenia). Reimbursement policies will align with State Fee-For-Service policies. Neighborhood is not permitted to collect rebates on these products. They will be paid for outside of any inpatient payment bundles so that the State can accept applicable rebates.
3. The administering facility/provider must submit the claim **after** the entire dose/infusion has been administered to the member.
4. All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes. Please refer to [Clinical Trials Payment Policy](#) for more information.
5. Medicaid
 - Neighborhood reserves the right to cover medications in the most administratively cost effective way that does not interfere with positive clinical outcomes. This includes, but is not limited to initiatives such as Site of Care (receiving infusion medications at the most cost effective site when clinically appropriate), White Bagging (specialty pharmacy ships the medication directly to the provider's office), Brown Bagging (patient receives the medication from the specialty pharmacy and takes it to their provider for administration), etc.
6. All other reimbursement billing requirements stated in Neighborhood's Medically Administered Medications Payment Policy and Pharmaceuticals NDC Billing Requirements Policy need to be followed.

References:

1. NHPRI Formulary and Payment Management Policy and Procedure.

Claim Submission

Billable services are subject to contractual agreements, when applicable. Providers are required to submit complete claims for payment within contractually determined timely filing guidelines.

Coding must meet standards defined by the American Medical Association's Current Procedural Terminology Editorial Panel's (CPT®) codebook, the International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification (ICD-10-CM), and the Healthcare Common Procedure Coding System (HCPCS) Level II.



Documentation Requirements

Neighborhood reserves the right to request medical records for any service billed. Documentation in the medical record must support the service(s) billed as well as the medical necessity of the service(s). Neighborhood follows CMS standards for proper documentation requirements.

Member Responsibility

Commercial plans include cost sharing provisions for coinsurance, copays, and deductibles. Members may have out of pocket expenses based on individual plan selection and utilization. Please review cost sharing obligations or contact Member Services prior to finalizing member charges.

For Dual CONNECT (Coordination only D-SNP plan), providers must submit claims to Neighborhood and any remaining copays/coinsurance amounts and Medicaid covered benefits to EOHHS for reimbursement.

Disclaimer

This payment policy is informational only and is not intended to address every situation related to reimbursement for healthcare services; therefore, it is not a guarantee of reimbursement.

Claim payments are subject to the following, which include but are not limited to: Neighborhood Health Plan of Rhode Island benefit coverage, member eligibility, claims payment edit rules, coding and documentation guidelines, authorization policies, provider contract agreements, and state and federal regulations. References to CPT or other sources are for definitional purposes only.

Neighborhood processes Dual CONNECT in accordance with CMS Medicare guidelines. Neighborhood processes INTEGRITY for Duals in accordance with CMS Medicare and Rhode Island Executive Office of Health and Human Services (RI EOHHS) guidelines. Refer to [CMS Medicare guidance](#) and [RI EOHHS Provider Manuals & Guidelines](#) for rules and claims processing policies.

This policy may not be implemented exactly the same way on the different electronic claims processing systems used by Neighborhood due to programming or other constraints; however, Neighborhood strives to minimize these variations.

The information in this policy is accurate and current as of the date of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to update this payment policy at any time. All services billed to Neighborhood for reimbursement are subject to audit.



Document History

Date	Action
09/01/2026	Updated policy template to include new lines of business. Updated Member Responsibility and Disclaimer language.
12/11/2024	Policy Review Date. No content changes.
03/23/2023	Policy Review Date