

Genetix Biotherapeutics Gene Therapy

Sample Letter of Intent

PLEASE NOTE:

This sample letter, provided by Genetix Biotherapeutics Inc., is for informational and reference purposes only, providing an example of information that may be helpful to consider when initiating gene therapy coverage and reimbursement discussions with payers.

Use of this information does not constitute medical or legal advice. Qualified Treatment Centers (QTCs) are responsible for their contracting and reimbursement matters and their communications with payers.

When sending information to a third-party payer for review, ensure that you submit under your institution's letterhead.

Potential Resources for Reference in Developing Letter of Intent:

- U.S. Prescribing Information available at [genetixbiotx.com/#therapies](https://www.genetixbiotx.com/#therapies)
- U.S. Medication Guides and Patient Information available at [genetixbiotx.com/#therapies](https://www.genetixbiotx.com/#therapies)
- Billing & Coding Guides available on [genetixcares.com/#hcps](https://www.genetixcares.com/#hcps)

For questions regarding additional gene therapy information, please reach out to your local Genetix Biotherapeutics Account Executive.

The following is a sample letter of intent that may be customized to your center. Use of this sample letter is not required.

[Today's Date]

[Name of Insurance Company] [Address of Insurance Company] [City], [State], [Zip Code]

Attention: Provider Network Relations / Gene Therapy Contracting

Re: Reimbursement Considerations for [Genetix Biotherapeutics Gene Therapy Product Name] Treatment

Dear [Payer Contact Name],

I am writing on behalf of [QTC Name], which [has been qualified for OR is in the process of being qualified for], and intends to offer, [Genetix Biotherapeutics Gene Therapy Product Name] as a treatment option for appropriate patients at our center, in accordance with the FDA-approved use. Coverage and reimbursement of this gene therapy were not included or considered under the existing terms of our current agreement. To ensure timely access to treatment for appropriate [Payer Name] members, we would like to begin discussions regarding reimbursement for [Genetix Biotherapeutics Gene Therapy Product Name] and the associated services.

[Genetix Biotherapeutics Gene Therapy Product Name] Overview

[Brief description of the product, which may include the following (not exhaustive):

- FDA-approved indication
- Treatment process / steps
- Expected setting(s) of care
- Gene therapy product list/invoice price]

[QTC Name] Relevant Experience & Expertise

[Summary of relevant treatment center experience with gene therapy, which may include the following (not exhaustive):

- Participation in cell and gene therapy clinical trials
- Experience with transplant and currently approved cell and gene therapies
- Implementation of a designated autologous cell / gene therapy team and relevant protocols throughout the treatment process (incl. FACT accreditation status)
- Experience in product's FDA-approved indication
- QTC qualification / activation status for the gene therapy product(s) by Genetix Biotherapeutics]

Proposed Reimbursement Considerations

[Proposed reimbursement terms for treatment with the gene therapy product for the FDA-approved indication. If case rate reimbursement applies, consider including the following (not exhaustive):

- Applicable setting(s) of care (e.g., inpatient, outpatient)
- Anticipated procurement method (SP vs. SD)
- Anticipated duration of a typical case
- Included components of ex-vivo gene therapy-related care (e.g., pre-treatment, cell collection(s), inpatient stay, product infusion)
- Gene therapy product carve-in or carve-out and related terms
- Proposed base rate and outlier terms]

[QTC Name] looks forward to discussing the proposed reimbursement approach for [Genetix Biotherapeutics Gene Therapy Product Name] and associated services with designated [Payer Name] representatives. Thank you for your attention to this matter.

Sincerely,

[Designated QTC Contact Name and Signature]

[Designated QTC Contact's Phone, Email, and Address]