Drug and Biologic Coverage Policy

Effective Date 2/1/2022
Next Review Date… 2/1/2023
Coverage Policy Number 1315

Interferon Therapy

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Please refer to coverage policy (CP) 1403, Oncology Medications, for all oncology criteria for interferon and pegylated interferon therapy.

Interferon Therapy includes the following products:

- Pegylated Interferon Therapy:
  - Peginterferon alfa-2a (**Pegasys®**) – **Preferred Brand** [Employer group plans only, and plans using Advantage Prescription Drug List]
  - Peginterferon alfa-2b (**Peg-Intron®**) – **Preferred Brand** [Employer group, Individual & Family Plans]
- Interferon Therapy:
  - Interferon alfa-n3 (**Alferon® N**)
  - Interferon alfa-2b (**Intron® A**)

Pegylated interferon therapy (Pegasys, Peg-Intron) is considered medically necessary when use is defined by ANY of the following:

- **Chronic active hepatitis B** and EITHER of the following:
  - Individual is 3 years of age and older for Pegasys
  - Individual is 18 years of age and older for Peg-Intron

(Authorization is for 48 weeks.)

- **Chronic Hepatitis C**
  - **Pegasys**: HCV infection in a pediatric individual (age 5-17 years old) with or without ribavirin **AND** previously untreated with interferon alfa (*Treatment duration authorization = 48 weeks*)
  - **PegIntron:** HCV infection in a pediatric individual (age 3-17 years old) with ribavirin (*Treatment duration authorization = 48 weeks*)

- **Essential thrombocythemia (ET)**

Interferon alfa-2b (Intron A) is considered medically necessary when use is defined by ANY of the following:

- **Chronic active hepatitis B**, AND:
  - Individual is 1 year of age and older

  (Authorization is for 24 weeks.)

- **Chronic Hepatitis C**
  - HCV infection in a pediatric individual (age 3-17 years old) in combination with ribavirin **AND** previously untreated with interferon alfa (*Treatment duration authorization for genotype 1 = 48 weeks; genotype 2 and 3 = 24 weeks*)

- **Essential thrombocythemia (ET)**
- **Condylomata acuminate** and ALL of the following:
  - Individual is 18 years of age and older
  - Intralesional treatment
  - Documented failure, contraindication per FDA label, or intolerance of podofilox

Interferon alfa-n3 (**Alferon N**) **is considered medically necessary when use is defined by EITHER of the following:**

- **Condylomata acuminate** and ALL of the following:
  - Individual is 18 years of age and older
  - Intralesional treatment
  - Documented failure, contraindication per FDA label, or intolerance of podofilox
- **Recurrent respiratory papillomatosis** (recurrent laryngeal papillomas, juvenile laryngeal papillomatosis), AND
  - Adjuvant treatment to surgery

Initial authorization is up to 12 months unless otherwise stated.

Interferon Therapy products are considered medically necessary for continued use when the individual continues to meet the initial criteria.

Reauthorization is up to 12 months unless otherwise stated.

Interferon Therapy products are considered experimental, investigational, or unproven for treatment of any other use including the following (this list may not be all inclusive):

- Bechet's disease
- Chronic uveitis
- Hepatitis E
- Idiopathic thrombocytopenic purpura (adults, adolescents, children)
- Middle East respiratory syndrome
- Peyronie's disease
- Vernal keratoconjunctivitis
- West Nile virus infection

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to Interferon Therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indication (for non-Hepatitis C and non-oncology indications)

Brand Name	Approved Indication
Pegylated Interferon Therapy	
Pegasys (peginterferon alfa-2a)	**Chronic Hepatitis B (CHB)** Adult Patients: Pegasys is indicated for the treatment of adults with HBeAg-positive and HBeAg-negative CHB infection who have compensated liver disease and evidence of viral replication and liver inflammation. Pediatric Patients: Pegasys is indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT). **Chronic Hepatitis C (CHC)** Pegasys, as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. For information about the safe and effective use of other HCV antiviral drugs to be used in combination with Pegasys, refer to their prescribing information. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs. Limitations of Use: • Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa. • Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.
Peg-Intron (peginterferon alfa-2b)	An antiviral indicated for treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease. All other covered uses are non-FDA labeled uses. PegIntron, as part of a combination regimen, is indicated for the treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease. • PegIntron in combination with Rebetol® (ribavirin) and an approved Hepatitis C Virus (HCV) NS3/4A protease inhibitor is indicated in adult patients with HCV genotype 1 infection (see labeling of the specific HCV NS3/4A protease inhibitor for further information). • PegIntron in combination with Rebetol is indicated in patients with genotypes other than 1, pediatric patients (3-17 years of age), or in patients with genotype 1 infection where use of an HCV NS3/4A protease inhibitor is not warranted based on tolerability, contraindications or other clinical factors. PegIntron monotherapy should only be used in the treatment of CHC in patients with compensated liver disease if there are contraindications to or significant intolerance of Rebetol and is indicated for use only in previously untreated adult patients. Combination therapy provides substantially better response rates than monotherapy.

Brand Name	Approved Indication
Interferon Therapy	
Alferon N (interferon alfa-n3)	Alferon N is indicated for the intralesional treatment of external genital and perianal exophytic warts (condylomata acuminate) due to human papillomavirus (HPV) in adults.
Intron A (interferon alfa-2b)	**Chronic Hepatitis B** Intron A is indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. **Chronic Hepatitis C** Intron A is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that Intron A therapy can produce clinically meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration. A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of Intron A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis C: • No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation • Bilirubin - Less than or equal to 2 mg/dL • Albumin - Stable and within normal limits • Prothrombin Time - Less than 3 seconds prolonged • WBC - Greater than or equal to 3000/mm3 • Platelets - Greater than or equal to 70,000/mm3 Serum creatinine should be normal or near normal. Prior to initiation of Intron A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at Weeks 1 and 2 following initiation of Intron A therapy, and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment (see Dosage and Administration). Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of Intron A treatment and TSH testing should be repeated at 3 and 6 months (see Precautions, Laboratory Tests). Intron A in combination with Rebetol® is indicated for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. See Rebetol prescribing information for additional information. **Condylomata Acuminata** Intron A is indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal area. The use of this product in adolescents has not been studied.

Recommended Dosing

FDA Recommended Dosing

<table>
<tr><th>Brand Name</th><th>FDA Recommended Dosing</th></tr>
<tr><td colspan="2">Pegylated Interferon Therapy</td></tr>
<tr><td>Pegasys
(peginterferon alfa-2a)</td><td>
Chronic Hepatitis B (CHB)
Adult Patients: The recommended Pegasys dosage in adults with CHB is 180 mcg subcutaneously once weekly in the thigh or abdomen for 48 weeks.

Pediatric Patients: The recommended Pegasys dosage in pediatric patients for HBeAg-positive CHB is 180 mcg/1.73 m2 x BSA subcutaneously once weekly to a maximum dose of 180 mcg. The recommended duration of therapy is 48 weeks.

Maintain the recommended pediatric dosage through the entire duration of therapy in patients who turn 18 years of age during therapy.

Adult Patients with Chronic Hepatitis C
Dosage in Adults with CHC without HIV Coinfection
Table 1 displays the recommended dosage and duration of Pegasys and other HCV antiviral drugs in adults with CHC (without HIV coinfection) based on HCV genotype.

For treatment of HCV genotype 1 with Pegasys in combination with ribavirin or alone, discontinuation of treatment is recommended if at least a 2 $\log_{10}$ reduction from baseline in HCV RNA has not been demonstrated by 12 weeks of therapy or if undetectable HCV RNA has not been achieved after 24 weeks of therapy. Refer to the prescribing information for specific HCV antiviral drugs used in combination with Pegasys for information on stopping therapy based on treatment response.

Immediately discontinue Pegasys for hepatic decompensation (Child-Pugh score greater than 6 [class B and C]).

Table 1 – Recommended Adult Dosage for Pegasys for CHC Infection[1]
<table>
<tr><th>Hepatitis C Virus Genotype</th><th>Pegasys Dosage</th><th>Pegasys Duration</th></tr>
<tr><td>Genotypes 1, 4*</td><td rowspan="2">180 mcg subcutaneous injection in thigh or abdomen once weekly</td><td rowspan="2">Refer to the prescribing information of HCV antiviral drugs</td></tr>
<tr><td>Genotypes 2, 3**</td></tr>
<tr><td>Genotypes 5, 6</td><td colspan="2">There is insufficient data for dosage recommendations</td></tr>
</table>
[1] If Pegasys is used in combination with other antiviral drugs for CHC, refer to the prescribing information of the other HCV antiviral drugs for the recommended dosage of the other HCV antiviral drugs and duration of the entire treatment regimen.
* If Pegasys and ribavirin are used without other HCV antiviral drugs the recommended duration of therapy is 48 weeks.
** If Pegasys and ribavirin are used without other HCV antiviral drugs the recommended duration of therapy is 24 weeks.

If Pegasys monotherapy is used for treatment of CHC, the recommended Pegasys dosage is 180 mcg via subcutaneous injection in thigh or abdomen once weekly for 48 weeks.

Dosage in Adults with CHC with HIV Coinfection
The recommended Pegasys dosage in adults with CHC and HIV coinfection is 180 mcg subcutaneously once weekly in the thigh or abdomen. If Pegasys is used in combination with other antiviral drugs, refer to the prescribing information of the other HCV antiviral drugs for the recommended dosage of the other HCV antiviral drugs and duration of the
</td></tr>
</table>

<table>
<tr><th>Brand Name</th><th>FDA Recommended Dosing</th></tr>
<tr><td></td><td>entire treatment regimen (including Pegasys). If Pegasys and ribavirin are used without other HCV antiviral drugs, the recommended duration of therapy is 48 weeks (regardless of HCV genotype).

<u>Pediatric Patients with CHC</u>
Pegasys is administered as 180 mcg/1.73 m^2 x BSA subcutaneously once weekly, to a maximum dose of 180 mcg, and should be given in combination with ribavirin. The recommended treatment duration for patients with genotype 2 or 3 is 24 weeks and for other genotypes is 48 weeks. Patients who initiate treatment prior to their 18th birthday should maintain the recommended pediatric dosage (not the adult dosage) through the completion of therapy. Refer to the prescribing information of ribavirin for the recommended dosage and duration.</td></tr>
<tr><td>Peg-Intron (peginterferon alfa-2b)</td><td>An antiviral indicated for treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease. All other covered uses are non-FDA labeled uses.

**Refer to the prescribing information (product label) for complete dosing information. The following is from the “Highlights of Prescribing Information” section of the product label.
• PegIntron is administered by subcutaneous injection.
<table>
<tr><td></td><td>PegIntron Dose (Adults)*</td><td>PegIntron Dose (Pediatric Patients)</td><td>Rebetol Dose* (Adults)</td><td>Rebetol Dose (Pediatric Patients)</td></tr>
<tr><td>PegIntron Combination Therapy</td><td>1.5 mcg/kg/week</td><td>60 mcg/m^2/week</td><td>800-1400 mg orally daily with food</td><td>15 mg/kg/day orally with food in 2 divided doses</td></tr>
</table>
* Refer to Tables 1-7 of the Full Prescribing Information

• Dose reduction is recommended in patients experiencing certain adverse reactions or renal dysfunction.</td></tr>
<tr><td colspan="2">Interferon Therapy</td></tr>
<tr><td>Alferon N (interferon alfa-n3)</td><td>The recommended dose of Alferon N for the treatment of condylomata acuminata is 0.05 ml (250,000 IU) per wart. Alferon N should be administered twice weekly for up to 8 weeks. The maximum recommended dose per treatment session is 0.5 ml (2.5 million IU).</td></tr>
<tr><td>Intron A (interferon alfa-2b)</td><td>Condyloma Acuminatum
The recommended dose is 1.0 million IU per lesion in a maximum of 5 lesions in a single course. The lesions should be injected three times weekly on alternate days for 3 weeks. An additional course may be administered at 12 to 16 weeks.

Chronic Hepatitis B
<u>Adult Patients:</u>
The recommended dose of INTRON A for the treatment of chronic hepatitis B is 30 to 35 million IU per week, administered subcutaneously or intramuscularly, either as 5 million IU daily (QD) or as 10 million IU three times a week (TIW) for 16 weeks.

<u>Pediatric Patients:</u>
The recommended dose of INTRON A for the treatment of chronic hepatitis B is 3 million IU/m2 three times a week (TIW) for the first week of therapy followed by dose escalation to 6 million IU/m2 TIW (maximum of 10 million IU TIW) administered subcutaneously for a total duration of 16 to 24 weeks.

Chronic Hepatitis C</td></tr>
</table>

<table>
<tr><th>Brand Name</th><th>FDA Recommended Dosing</th></tr>
<tr><td></td><td>The recommended dose of Intron A for the treatment of chronic hepatitis C is 3 million IU three times per week (TIW) administered subcutaneously or intramuscularly. In patients tolerating therapy with normalization of ALT at 16 weeks of treatment, Intron A therapy should be extended to 18 to 24 months (72 to 96 weeks) at 3 million IU TIW to improve the sustained response rate (see Clinical Pharmacology, Chronic Hepatitis C). Patients who do not normalize their ALTs or have persistently high levels of HCV RNA after 16 weeks of therapy rarely achieve a sustained response with extension of treatment. Consideration should be given to discontinuing these patients from therapy.

When Intron A is administered in combination with Rebetol® (ribavirin), patients with impaired renal function and/or those over the age of 50 should be carefully monitored with respect to the development of anemia. See Rebetol prescribing information for dosing when used in combination with Rebetol for adults and pediatric patients.

Dosage Forms for This Indication
<table>
<tr><th>Dosage Form</th><th>Concentration</th><th>Route</th><th>Fixed Doses</th></tr>
<tr><td>Solution 18 MIU multidose</td><td>6 MIU/mL</td><td>IM, SC</td><td>N/A</td></tr>
</table>

Dose Adjustment: If severe adverse reactions develop during Intron A treatment, the dose should be modified (50% reduction) or therapy should be temporarily discontinued until the adverse reactions abate. If intolerance persists after dose adjustment, Intron A therapy should be discontinued.</td></tr>
</table>

General Background

Pharmacology

Interferon alfa is a family of proteins that possess antiviral, antitumor and immunomodulating effects. Generally, interferons exert their cellular activities by binding to specific membrane receptors on the cell surface. Plasma concentrations of interferon below the detection limit of the assay, that is, less than or equal to 3 IU/ml were observed in a study of intralesional use of interferon alfa-n3 for the treatment of condylomata acuminate.

There is no convincing data to indicate a significant clinical difference between the various alpha interferons. Pegylated interferons including interferon alfa-2a and interferon alfa-2b are pure clones of single interferon subspecies. In pegylated interferons, polyethylene glycol (PEG) is attached to interferon as a protein modifying agent to decrease renal clearance and extend duration of action. This allows for once-weekly administration. Peginterferon alfa-2a has a mean systemic clearance approximately 100-fold lower than for interferon alfa-2a. The time to maximum serum concentration occurs between 72–96 hours. Peginterferon alfa-2b has an approximately seven-fold lower mean apparent clearance and a five-fold greater mean half-life than interferon alfa-2b, allowing a reduced dosing frequency.

Professional Societies/Organizations

Essential Thrombocythemia (ET)

The National Comprehensive Cancer Network (NCCN) has published guidelines for myeloproliferative neoplasms (MPNs). MPNs are disorders of the hematopoietic system that include essential thrombocythemia (ET). Characteristic to ET are significant thrombotic and hemorrhagic complications, and increased risks of conversion to acute myeloid leukemia. The treatment goal is to reduce the risk of thrombohemorrhagic events. Use of cytoreductive therapy, including hydroxyurea and interferon alfa, is based on risks as identified by age, thrombosis history and cardiovascular risk factors. Routine monitoring of disease-related symptoms and need-assessment for cytoreductive therapy should be part of the treatment management plan for individuals with PV and ET. (NCCN, 2020)

The Nordic MPN (myeloproliferative neoplasms) Study Group has published a care program for individuals with essential thrombocytopenia, and primary myelofibrosis. Recommendations are based upon review of the

evidence for the diagnosis and treatment of patients with these diseases. In essential thrombocythemia (ET), interferon alfa is mentioned as first and second line treatment in persons less than 60 years of age. In individuals over 60 years of age, interferon alfa is considered as second line therapy. (Ahlstrand, 2017)

Chronic Hepatitis B
The American Association for the Study of Liver Disease (AASLD) Practice Guidelines for chronic hepatitis B mention that pegylated interferon, entecavir and tenofovir are first line therapies in this disease state. When evaluating therapeutic options, consideration should be given to the safety/efficacy and potential resistance of the drug, as well as, its direct and indirect costs. Other factors to guide treatment selection include the preferences of the prescriber, patient, and in women, consideration of family planning. The organization does give preference to pegylated interferon over nonpegylated forms for simplicity of dosing regimen. (Terrault, 2018)

Peyronie's Disease
The American Urological Association (AUA) Practice Guidelines for Peyronie's disease state that clinicians may administer intralesional interferon alfa-2b to patients with Peyronie's disease. This statement was provided as a moderate recommendation with an evidence strength, grade C. The AUA recommendation was based on one randomized controlled trial of moderate quality (n=117), one randomized design without a placebo group (n=30), and eight observational studies. Of the two randomized trials taken into consideration, only one demonstrated statistically significant changes in Peyronie's disease as a result of interferon therapy. In this study, patients who received interferon therapy achieved an average curvature improvement of nine degrees compared to placebo. (Nehra, 2015)

Off Label Uses
The American Hospital Formulary Service (AHFS) Drug Information 2020 Edition supports the following off-label uses: acute hepatitis C virus, chronic hepatitis D virus, chronic hepatitis E virus infections, and recurrent respiratory papillomatosis (recurrent laryngeal papillomas, juvenile laryngeal papillomatosis) as adjunct to surgery. However, interferon alpha therapy is not recommended in the following area: Middle East Respiratory Syndrome. (AHFS, 2020)

Experimental, Investigational, Unproven Uses
Interferon alfa therapy in neuroinvasive West Nile Virus has not been demonstrated efficacious in controlled clinical studies. (AHFS, 2020)

Pegylated interferon alfa has been used for the treatment of chronic hepatitis E virus infection in solid organ transplant patients however its use has not been substantiated by controlled clinical trials of significant size demonstrating efficacy. The available clinical literature is primarily limited to trials enrolling less than five patients with inconsistent virologic response data and uncertainty to the curative agent. (AHFS, 2020)

Pegylated interferon alfa has been used in combination with ribavirin for the treatment of Middle East respiratory syndrome caused by the Middle East respiratory syndrome coronavirus. The Center for Disease Control has not identified a specific treatment for this viral infection. The available data for this indication is limited to a single retrospective cohort study with no significant difference in survival after 28 days between individuals who received interferon therapy and those who received supportive care. (AHFS, 2020)

Interferon in Peyronie's disease was the subject of a systematic review in 2007, which used Oxford criteria and analyzed intra-plaque injection therapies. Of the seven interferon studies reviewed, six were deemed level 4 evidence (case series or poor-quality cohort or case-control studies), while only one was considered level 1 evidence (meta-analysis or narrow confidence interval randomized, controlled trials). The authors call attention to factors which contribute to difficulty in conducting quality studies in this disease, such as the heterogeneity of patients enrolled in studies of Peyronie's, due to the natural phases of the disease, as well as a lack of agreement as to what are the important outcomes to assess and exactly how these should be evaluated. The studies available for evaluation are not conducted in a controlled manner and are often under powered. The review concludes that although the vast majority of studies for treatment of Peyronie's have reported positive outcomes, the data is weak and does not support the findings. (Russell, 2007)

Interferon alfa use in children and adolescents with ITP is no longer supported due to the paucity of evidence of efficacy and an abundance of reports of toxicities. In the adult population with ITP, available evidence confirms that interferon alfa is not effective and results in a disproportionate amount of toxicities. (Provan, 2010)

There is insufficient evidence in the peer-reviewed published scientific literature to support safety and efficacy of interferon use in Behcet's disease, chronic uveitis and vernal keratoconjunctivitis.

Coding/ Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9214	Injection, interferon alfa-2b, recombinant, 1 million units

References

1. Alferon N (package insert). Philadelphia, PA: Hemispherx Biopharma, Inc. July 2004.
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