Alferon N

Description

Alferon N (interferon alfa-N3)

Background
Interferons are naturally occurring proteins with antiviral, antiproliferative and immunoregulatory properties. They are produced and secreted in response to viral infections and to a variety of other synthetic and biological inducers. Four major families of interferons have been identified: alpha, beta, gamma and omega (1).

Binding of interferon to membrane receptors initiates a series of events including induction of protein synthesis. These actions are followed by a variety of cellular responses, including inhibition of virus replication and suppression of cell proliferation. Immunomodulation, including enhancement of phagocytosis by macrophages, augmentation of the cytotoxicity of lymphocytes and enhancement of human leukocyte antigen expression occurs in response to exposure to interferons. One or more of these activities may contribute to the therapeutic effect of interferon (1).

Regulatory Status
FDA-approved indication: Alferon N (interferon alfa-n3) is indicated for the intralesional treatment of refractory or recurring external condylomata acuminata in patients 18 years of age or older (1).

The physician should select patients for treatment with Alferon N injection after consideration of a number of factors: the locations and sizes of the lesions, past treatment and response thereto,
and the patient's ability to comply with the treatment regimen. Alferon N injection is particularly useful for patients who have not responded satisfactorily to other treatment modalities, e.g., podophyllin resin, surgery, laser or cryotherapy (1).

Fever and other "flu-like" symptoms have been associated with Alferon N therapy and should be used cautiously in patients with debilitating medical conditions such as cardiovascular disease (e.g., unstable angina and uncontrolled congestive heart failure), severe pulmonary disease (e.g., chronic obstructive pulmonary disease), or diabetes mellitus with ketoacidosis (1).

Alferon N injection should be used cautiously in patients with coagulation disorders (e.g., thrombophlebitis, pulmonary embolism and hemophilia), severe myelosuppression, or seizure disorders (1).

Safety and effectiveness have not been established in patients below the age of 18 years (1).

**Related policies**
Actimmune, Intron A, Pegasys, Peginteron

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Alferon N may be considered **medically necessary** for patients 18 years of age or older for treatment of condylomata acuminata.

Alferon N may be considered **investigational** for patients below 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

Condylomata acuminata
Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Alferon N (interferon alfa-n3) is indicated for the intralesional treatment of refractory or recurring external condylomata acuminata in patients 18 years of age or older. Alferon N therapy should be used cautiously in patients with cardiovascular disease, severe pulmonary disease, and diabetes mellitus with ketoacidosis, coagulation disorders, severe myelosuppression, or seizure disorders. Safety and effectiveness have not been established in patients below the age of 18 years (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Alferon N while maintaining optimal therapeutic outcomes.

References
   http://www.hemispherx.net/content/products/alferon_insert.htm._Accessed on 12/20/2015

Policy History
Date Action
August 2011  Alferon N separated into its own criteria. Chronic granulomatous disease and inflammatory pulmonary fibrosis removed from criteria due to either being an investigational use or no current clinical sources supporting its use. Multiple myeloma added to criteria as medical practice and AHFS support this indication.

November 2011  Updated the criteria for chronic myelogenous leukemia to align with the NCCN guidelines for the diagnosis and treatment of CML.

December 2012  Annual editorial review and reference update

March 2014  Annual editorial review and reference update
Removal of the following off-label indications as they are not supported by clinical literature for Alferon N: AIDS-related Kaposi’s sarcoma, follicular lymphoma, hairy cell leukemia, malignant melanoma, and chronic myelogenous leukemia (CML).

March 2015  Annual editorial review and reference update

December 2015  Annual review

March 2016  Annual editorial review
Policy number changed from 5.04.02 to 5.21.02

June 2017  Annual editorial review

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Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 22, 2017 and is effective on July 1, 2017.