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5.21.002

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 29, 2011
Subject:	Alferon N	**Page:**	1 of 4

Last Review Date: March 8, 2024

Alferon N

Description

Alferon N (interferon alfa-N3)

Background
Interferons are naturally occurring small proteins and glycoproteins produced and secreted by cells in response to viral infections and to synthetic or biological inducers. They exert their cellular activities by binding to specific membrane receptors on the cell surface. Once bound to the cell membrane, interferons initiate a complex sequence of intracellular events including the following: induction of certain enzymes, suppression of cell proliferation, immunomodulating activities such as enhancement of the phagocytic activity of macrophages and augmentation of the specific cytotoxicity of lymphocytes for target cells, and inhibition of virus replication in virus-infected cells (1).

Alferon N (interferon alpha-n3) is a protein that induces protein synthesis by binding to specific membrane receptors, which leads to inhibition of virus replication and suppression of cell proliferation. The agent exerts its immunomodulation effect by enhancing macrophage phagocytosis and expression of human leukocyte antigen and augmenting lymphocyte cytotoxicity (2).

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 (2-3).

Alferon N injection should be used cautiously in patients with cardiovascular disease, coagulation disorders (e.g., thrombophlebitis, pulmonary embolism, and hemophilia), diabetes mellitus with ketoacidosis, severe pulmonary disease, severe myelosuppression, or seizure disorders (2).

The only role for interferon alpha-n3 at present is the intralesional treatment of condyloma acuminata, as an alternative to conventional regimens (e.g., podophyllin, cryotherapy) in unresponsive/intolerant patients. Interferon alfa-2b is also effective intralesionally in this setting and could be used in lieu of interferon alfa-n3 (2).

Safety and effectiveness of Alferon N have not been established in patients less than 18 years of age (2).

Related policies
Actimmune, Intron A, Pegasys, Pegintron

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** if the conditions indicated below are met.

Alferon N may be considered **investigational** 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

Same as above

Rationale

Summary

Alferon N (interferon alpha-n3) is a protein that induces protein synthesis by binding to specific membrane receptors, which leads to inhibition of virus replication and suppression of cell proliferation. The agent exerts its immunomodulation effect by enhancing macrophage phagocytosis and expression of human leukocyte antigen and augmenting lymphocyte cytotoxicity. Safety and effectiveness of Alferon N have not been established in patients less than 18 years of age (2).

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

References

1. Interferons. (2007, August 15). Retrieved February 16, 2021, from https://onlinelibrary.wiley.com/doi/abs/10.1002/9780471743989.vse9972
2. Interferon Alpha-n3. In: Dosing/Administration and Medication Safety [database on the Internet]. Greenwood Village (CO): IBM Corporation; 2020 [cited 2021 Feb 15]. Available from: www.micromedexsolutions.com.
3. Alferon N [package insert]. Philadelphia, PA: AIM ImmunoTech Inc.; October 2021.

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
June 2019	Annual review
June 2020	Annual review and reference update
March 2021	Annual editorial review Revised Background, Regulatory Status and Summary Sections
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.21.002
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.