RATIONALE FOR INCLUSION IN PA PROGRAM

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).
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, 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