SPECIALTY GUIDELINE MANAGEMENT

Alferon N Injection (interferon alfa-n3)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Alferon N Injection is indicated for the intralesional treatment of refractory or recurring external condylomata acuminata in patients 18 years of age or older.

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 (eg, podophyllin resin, surgery, laser or cryotherapy).

There have been no studies with this product in adolescents. This product is not recommended for use in patients less than 18 years of age.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Documentation (e.g., chart notes) of previous conventional therapies for condylomata acuminata

C. EXCLUSIONS

- Known anaphylactic sensitivity to mouse immunoglobulin, egg protein, or neomycin

D. CRITERIA FOR APPROVAL

1. Condylomata acuminata (genital warts)

Authorization of 4 months may be granted for members who are prescribed Alferon-N for the treatment of condylomata acuminata when ALL of the following criteria are met:

a. The member is 18 years of age or older
b. The condition has failed to respond to or recurred following at least one of the following CDC-recommended conventional therapies:
   i. podofilox (Condylox)
   ii. imiquimod (Aldara)
   iii. sinecatechins (Veregen)
   iv. podophyllin or podophyllum resin (Podocon-25)
   v. trichloroacetic acid (Tri-Chlor)
   vi. bichloroacetic acid
   vii. cryotherapy
   viii. surgical removal

E. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

1. Hemispherx BioPharma, Inc. Alferon-N. http://www.hemispherx.net/content/products/alferon_insert.htm. Accessed December 16, 2014.
2. AHFS Drug Information. http://online.lexi.com/lco. Accessed December 16, 2014.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at http://www.micromedexsolutions.com. Accessed December 16, 2014.
4. Workowski KA, Berman S; Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. *MMWR Recomm Rep*. 2010;59(RR-12):1-110.