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DIVISION OF INSURANCE

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Bulletin No. 97-09

To: **Commercial Health Insurers, Blue Cross and Blue Shield of Massachusetts (BCBSMA), Health Maintenance Organizations (HMOs)**

From: **Linda Ruthardt, Commissioner**

Re: **Coverage for Drugs Used for HIV/AIDS Treatment**

Date: **November 4, 1997**

As indicated in Bulletin No. 95-05, laws enacted in 1994 mandate that policies, certificates, evidences of coverage and contracts that provide coverage for prescription drugs must provide certain coverage for the off-label use of prescription drugs for treatment of HIV/AIDS: G.L. c. 175, §§ 47O and 47P; G.L. c. 176A, § 8Q; G.L. c. 176B, § 4P and G.L. c. 176G, § 4G. (Please note that St. 1996, c. 450, §§ 219, 222 renumbered the sections to replace G.L. c. 176A, § 8O with G.L. c. 176A, § 8Q.) The laws prohibit commercial health insurers, BCBSMA and HMOs from excluding coverage for drugs used for the treatment of HIV/AIDS on the grounds that the off-label use of the drug has not been approved by the federal Food and Drug Administration for that indication if the drug is recognized for treatment of HIV/AIDS by one of the standard reference compendia, by medical literature, or by the Division based upon the recommendations of an Advisory Panel established under G.L. c.175, § 47P.

In 1996, the Division issued Bulletin No. 96-05 to inform commercial health insurers, BCBSMA and HMOs that the Division accepted the Advisory Panel's recommendations and set forth a list of the off-label uses of specific drugs which are to be recognized for the treatment of HIV/AIDS. The Division also issued Bulletin No. 96-06 which indicated that the off-label uses of any antiretroviral drugs in any combination for the treatment of HIV/AIDS may not be denied at any stage of HIV infection.

The Advisory Panel developed new recommendations on May 12, 1997 to update the list of off-label uses of drugs for the treatment of HIV/AIDS. The recommendations included adding new drugs to the previously approved list set forth in Bulletin No. 96-05 and replacing certain previously approved indications set forth in Bulletin No. 96-05. The Division held an informational hearing on July 22, 1997 to hear testimony from all interested parties regarding the recommendations.

The Division accepts the Advisory Panel's recommendations and recognizes that the off-label uses of the prescription drugs for the treatment of HIV/AIDS submitted by the Advisory Panel on May 12, 1997 are required to be provided as of the date of this Bulletin. The attachment to this Bulletin updates Bulletins 96-05 and 96-06 and sets forth all the drugs (including the drugs required to be provided pursuant to Bulletin No. 96-05) that are mandated to be covered as of the date of this Bulletin. Also note that this Bulletin (Bulletin No. 97-09) may be updated by either adding or deleting items based upon consideration of new information submitted by the Advisory Panel or other parties to the Division. Any such changes will be communicated through future bulletins from the Division of Insurance. Any recommendations regarding the use of off-label drugs should be submitted to the Advisory Panel through the Health Unit at the Division of Insurance. Policyholders, subscribers, and members must be notified of the drugs covered under this law.

Questions regarding this bulletin should be directed to the Division of Insurance's Health Unit of the State Rating Bureau at (617) 521-7349.

Bulletin 97-09
Off-Label Uses of Prescription Drugs for the Treatment of HIV/AIDS

The following off-label uses of prescription drugs for the treatment of HIV/AIDS, as recommended to the Commissioner of Insurance by an advisory panel established according to M.G.L. c. 175 § 47P, are officially recognized as off-label uses mandated to be covered by commercial health insurers, BCBSMA and HMOs according to requirements of M.G.L. c. 175, § 47O, c. 176A, § 8Q, c. 176B, § 4P, and c. 176G, § 4G:

PRESCRIPTION	OFF-LABEL INDICATIONS
1. **Acyclovir**	For treatment and suppression of herpes simplex viruses and HIV infection.
2. **Alpha Interferon**	Adjunctive anti-viral therapy in the treatment of HIV infection.
3. **Albendazole**	For treatment of microsporidiosis.
4. **Anabolic steroids**	For treatment and maintenance of weight in HIV wasting syndrome and for treatment of HIV-related non-hypogonadal erectile dysfunction.
5. **Atovaquone**	For PCP prophylaxis.
6. **Azithromycin**	Treatment and prevention of Mycobacterial avium and other bacterial infections.
7. **Chlorhexidine mouthwash**	For treatment of HIV-related gingival disease.
8. **Ciprofloxin**	For bacterial infections associated with HIV infection.
9. **Clarithromycin**	Treatment and prevention of Mycobacterial avium and other bacterial infections.
10. **Dronabinol**	Nausea of any etiology and for treatment and maintenance of weight in HIV wasting syndrome.
11. **Erythropoetin**	HIV-associated anemia including, but not limited to, AZT-related anemia.
12. **Famciclovir**	For treatment of HIV family of virus.
13. **Fluconazole**	Treatment and prevention of diseases caused by susceptible fungi including doses higher than current label indications.
14. **Foscarnet**	CMV and herpes viral infection, including use of foscarnet in combination with ganciclovir and also intravitrial injections.
15. **Ganciclovir**	Intravenous use for CMV and herpes viral infection including use of ganciclovir in combination with foscarnet and also intravitrial injections. Oral use for the prevention and treatment of CMV infections alone or in combination with other active agents.

16. **G-CSF**	Documented or anticipated neutropenia.
17. **Hydroxyurea**	As an adjunctive antiretroviral agent to be used in combination with nucleoside analogs.
18. **Interleukin 2**	As an adjunctive immunomodulating agent in HIV-infected patients receiving anti-retroviral therapy.
19. **Itraconazole**	Treatment and prevention of diseases caused by susceptible fungi, including doses higher than current label indications.
20. **IVIG (Intravenous Immunoglobulins)**	For prevention of recurrent bacterial infections, for treatment of HIV-related thrombocytopenia and for thrombotic thrombocytopenic purpura (TTP).
21. **Ketoconazole**	Treatment and prevention of diseases caused by susceptible fungi, including doses higher than current label indications, and as a potentiator of saquinavir activity or possibly of other protease inhibitors.
22. **Paromomycin (Humatin)**	For treatment of cryptosporidiosis.
23. **Phenytoin**	Peripheral neuropathic pain.
24. **Serostim (Human Growth Hormone)**	For treatment and maintenance of weight in HIV wasting syndrome not responsive to other interventions.
25. **Tincture of opium**	For management of HIV-related diarrhea.
26. **Total Parenteral Nutrition (TPN)**	For treatment and maintenance of weight in HIV wasting syndrome not responsive to other interventions.

It is also important to note that the off-label uses of any antiretroviral drugs in any combination may not be denied at any stage of HIV infection.