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COMMISSIONER, INSURANCE

Bulletin No. 96-05

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: **April 5, 1996**

As indicated in Bulletin No. 95-05, laws enacted in 1994 mandate certain coverage for the off-label use of prescription drugs for the treatment of HIV/AIDS: St. 1994, c. 60, §§ 142, 144, 146, and 149 which added G.L. c. 175, §§ 47O and 47P; G.L. c. 176A, § 8O; G.L. c. 176B, § 4P and G.L. c. 176G, § 4G. This mandate is effective for all policies, certificates, evidences of coverage and contracts that provide coverage for prescription drugs which are issued or renewed on or after July 1, 1994.

Commercial health insurers, BCBSMA and HMOs are prohibited 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 addition, medically necessary services associated with the administration of these drugs are required to be covered.

The Division's advisory panel recommended that the off-label uses of the specific drugs set forth on the back of this bulletin be recognized for the treatment of HIV/AIDS pursuant to the mandate. The Division held a public session on March 12, 1996 for the purpose of hearing testimony from all interested parties regarding the recommendations.

Based upon the submitted information, the Division hereby approves the advisory panel's recommendations and recognizes that the noted off-label uses of these drugs for the treatment of HIV/AIDS shall be mandated to be covered as of the date of this bulletin. Please note that this list 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 Policy Unit at the Division of Insurance. Policyholders, subscribers, and members must be notified of the drugs covered under this law.

Any questions regarding this bulletin should be directed to the Division of Insurance's Health Policy Unit at (617) 521-7347.

Bulletin 96-05
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 that are mandated to be covered as of April 5, 1996 by commercial health insurers, BSBCMA and HMOs according to the requirements of M.G.L. c. 175, § 47O, c. 176A, § 8O, c. 176B, § 4P, and c. 176G, § 4G:

PRESCRIPTION	OFF-LABEL INDICATIONS
1. **Alpha Interferon**	Adjunctive anti-viral therapy in the treatment of HIV infection.
2. **Azithromycin**	Off-label indications for HIV infection, including, but not limited to, the conditions listed on an addendum to be developed at a future date by the Panel.
3. **Clarithromycin**	Off-label indications for HIV infection, including, but not limited to, the conditions listed on an addendum to be developed at a future date by the Panel.
4. **Dronabinol**	Nausea of any etiology.
5. **Erythropoetin**	HIV-associated anemia, including, but not limited to, AZT-related anemia.
6. **Fluconazole**	Treatment and prevention of diseases caused by susceptible fungi, including doses higher than current label indications.
7. **Foscarnet**	CMV and herpes viral infection, including use of foscarnet in combination with ganciclovir and also intravitreal injections.
8. **Ganciclovir**	Intravenous use for CMV and herpes viral infection, including use of ganciclovir in combination with foscarnet and also intravitreal injections. Oral use for the prevention and treatment of CMV infections alone or in combination with other active agents.
9. **G-CSF**	Documented or anticipated neutropenia.
10. **Itraconazole**	Treatment and prevention of diseases caused by susceptible fungi, including doses higher than current label indications.
11. **Ketoconazole**	Treatment and prevention of diseases caused by susceptible fungi, including doses higher than current label indications.
12. **Phenytoin**	Peripheral neuropathic pain.