Horizon BCBSNJ
Medical Necessity Guideline

Section	Drugs
Policy Number	
Effective Date	2/4/10
Review Date	

SPECIALTY GUIDELINE MANAGEMENT
HORIZON: Actimmune® (interferon gamma-1b)

IMPORTANT NOTE:

The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. ***Outpatient prescription drugs are not covered under all Horizon benefit plans.*** *If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

PROGRAM RATIONALE
The intent of the criteria is to ensure that patients follow selection elements established by Horizon Blue Cross Blue Shield (BCBS) of New Jersey medical policy.

FDA-APPROVED INDICATIONS
Chronic granulomatosis disease (CGD): Actimmune is indicated for reducing the frequency and severity of serious infections associated with CGD. [1,2]

Osteopetrosis: Actimmune is indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis.[1,2]

Compendial Uses:
The following indications are considered medically necessary uses for Actimmune:[2]

- Atopic dermatitis[2]
- Mycosis fungoides (MF) and Sezary syndrome (SS) according to the following criteria:[2,3]
  - Primary treatment as systemic biologic therapy in patients with stage IA to IIA with blood involvement, stage IIB to IV MF and SS. Used as indicated below:
    - Single agent for stage IA to IIA and stage III MF with blood involvement
    - Single agent or in combination with radiation therapy for stage IIB MF limited-extent tumor disease
    - Single agent or in combination with systemic retinoids, phototherapy, or photopheresis (with or without systemic retinoids) stage IA to IIB with large cell transformed MF, stage IIB MF (generalized tumor disease or limited-extent tumor disease with blood involvement) or SS
    - Single agent or in combination with skin-directed therapies (corticosteroids, carmustine, mechlorethamine hydrochloride, phototherapy, or total skin electron beam therapy) for stage III MF with no blood involvement

- May be used as adjuvant systemic biologic therapy after total skin electron beam therapy for stage IIB MF generalized tumor disease or limited tumor disease with blood involvement or large cell transformation or after chemotherapy for stage IV MF with bulky lymph nodes or visceral disease
- Systemic biologic therapy for patients with refractory or progressive MF, as a single agent or in combination with systemic retinoids, phototherapy, or photopheresis (with or without systemic retinoids).

ALGORITHMS

Figure 1: Referral for Actimmune

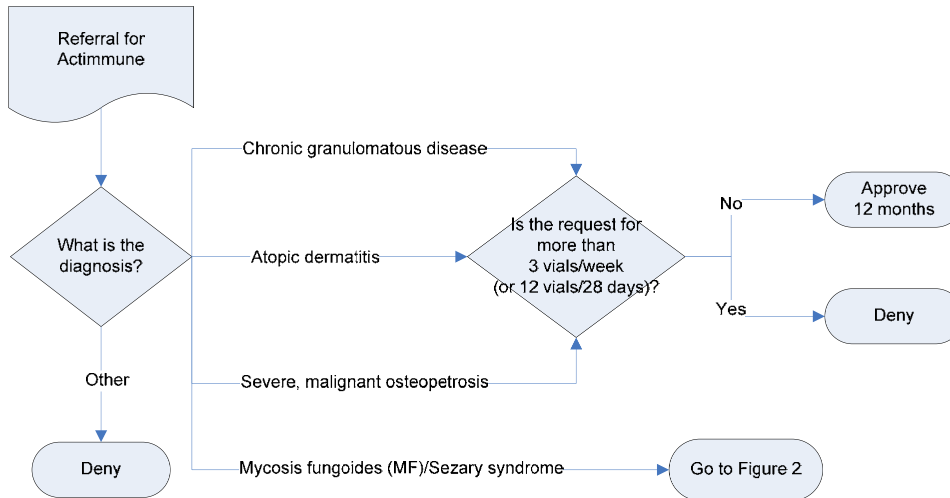
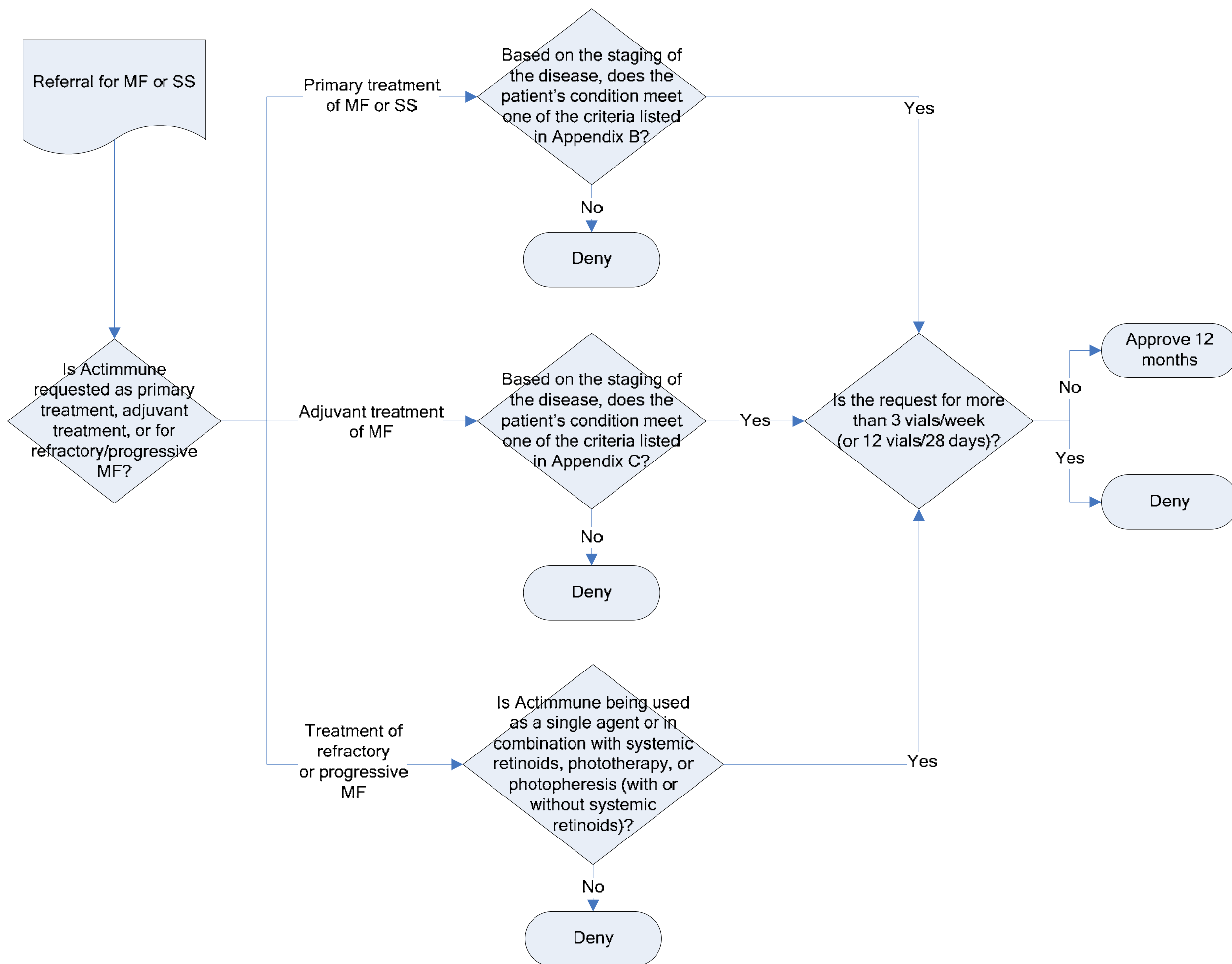


Figure2: Use of Actimmune for Mycosis Fungoides or Sezary Syndrome



Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

APPENDIX A: Abbreviation Key
MF = mycosis fungoides
SS = Sezary syndrome

APPENDIX B
Use of Actimmune as primary systemic biologic therapy for MF or SS is medically necessary according to the following criteria:

- As a single agent for stage IA to IIA and stage III mycosis fungoides with blood involvement
- As a single agent, or in combination with radiation therapy, for stage IIB MF limited-extent tumor disease
- As a single agent or in combination with systemic retinoids, phototherapy, or photopheresis (with or without systemic retinoids) for:
    - Stage IA to IIB with large cell transformed MF
    - Stage IIB MF (generalized tumor disease or limited-extent tumor disease with blood involvement)
    - SS
- Single agent or in combination with skin-directed therapies (corticosteroids, carmustine, mechlorethamine hydrochloride, phototherapy, or total skin electron beam therapy) for stage III MF with no blood involvement

APPENDIX C:
Use of Actimmune as adjuvant therapy for MF is medically necessary according to the following criteria:

- After total skin electron beam therapy for Stage IIB MF with:
    - Generalized tumor disease
    - Limited tumor disease with blood involvement
    - Large cell transformation
- After chemotherapy for stage IV MF with bulky lymph nodes or visceral disease

HISTORY
2/4/2010 Original Policy

REFERENCES
1. Actimmune [package insert]. Brisbane, CA: InterMune, Inc.; January 2009.
2. Horizon Medical Policy for Actimmune. https://services3.horizon-bcbsnj.com/hcm/MedPol2.nsf.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed on January 22, 2010.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

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