Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

Background Information:

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Medical Department Procedure Manual

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Title: mechlorethamine gel (Valchlor®)  Page 2 of 4

Background Information, continued:

Medication Summary

- Mechlorethamine gel (Valchlor®), a topical preparation of mechlorethamine (commonly known as nitrogen mustard), is an alkylating agent that inhibits rapidly proliferating cells. Mechlorethamine exerts its function by interfering with DNA replication, RNA transcription, and nucleic acid function, thereby impairing cellular function.

- Mechlorethamine gel (Valchlor®) is indicated for the topical treatment of Members with Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma who have received prior skin-directed therapy.

Coverage Guidelines

- Member must be eligible and have applicable benefit coverage.

- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members less than 18 years of age.

- Members who are pregnant.

- Members who have had experienced a severe hypersensitivity to mechlorethamine.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.

- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
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Procedure:

1.0 Request for initial therapy of Mechlorethamine gel (Valchlor®) requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying the following:

1.1 Requesting prescriber is an oncologist or hematologist; AND

1.2 Member has been diagnosed with either Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma; AND

1.3 Member has experienced failure, intolerance or has contraindication to at least two (2) alternative skin-directed therapies including:

1.3.1 Topical corticosteroids;
1.3.2 Topical retinoids;
1.3.3 Compounded mechlorethamine 0.02% ointment;
1.3.4 Imiquimod 5% topical cream;
1.3.5 Local radiation therapy;
1.3.6 Phototherapy;

1.4 If criteria are met, request may be approved for six (6) months.

2.0 Request for continuation of therapy with Mechlorethamine gel (Valchlor®) requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying the following:

2.1 Progress notes demonstrating Member is having beneficial effect from therapy (lack of disease progression or disease improvement);

2.2 Member is not experiencing unacceptable toxicity;

2.3 If criteria are met, request may be approved for six (6) months.
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References:
