Clinical Policy: Sulfacetamide Sodium/Sulfur (Sumadan)

Reference Number: HIM.PA.145
Effective Date: 10.30.17
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sulfacetamide sodium/sulfur (Sumadan®) is a sulfonamide antibiotic and topical antimicrobial and keratolytic agent.

FDA Approved Indication(s)

Sumadan is indicated for the treatment of:

- Acne vulgaris
- Acne rosacea
- Seborrheic dermatitis

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all)**:**

1. Diagnosis of acne vulgaris;
2. Age ≥ 12 years;
3. Failure of ≥ 2 of the following topical preparations, each from different medication classes and each trialed for ≥ 2 months, unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Topical antibiotics: clindamycin, erythromycin;
   b. Topical anti-infectives: benzoyl peroxide;
   c. Topical retinoids: tretinoin;
4. Dose does not exceed 1 tube per month.

Approval duration: 12 months

B. Acne Rosacea (must meet all)**:**

1. Diagnosis of acne rosacea;
2. Age ≥ 12 years;
3. Failure of a trial of a metronidazole topical product unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 1 tube per month.

Approval duration: 12 months

C. Seborrheic Dermatitis (must meet all)**:**

1. Diagnosis of seborrheic dermatitis;
2. Age ≥ 12 years;
3. Failure of ≥ 2 topical preparations (e.g., ketoconazole, ciclopirox, selenium sulfide) each trialed for ≥ 1 month, unless all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 1 tube per month.

Approval duration: 12 months

D. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tube per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
N/A

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clindamycin (Cleocin T®, Clindamax®, Clindagel®, Evoclin®)	Gel, pledget, lotion, solution: apply a thin film TOP BID	N/A

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Gel, foam: apply TOP QD	
erythromycin (Erygel®, Ery®)	Gel: apply sparingly as a thin film over affected area TOP QD or BID Ointment, solution: apply to affected area TOP BID Pads: rub pad over affected areas BID	N/A
benzoyl peroxide	Topical formulations: apply sparingly TOP QD; may increase up to TID if needed Topical cleansers: wash TOP QD or BID	N/A
tretinoin (Retin-A®, Retin-A Micro®)	Apply TOP QHS	N/A
metronidazole (MetroCream®, Rosadan®, Metrogel®, MetroLotion®)	Apply thin film TOP to affected areas QD or BID	N/A
ketoconazole (Extina®)	Cream, foam: apply to affected area TOP BID for 4 weeks Gel: apply to affected area TOP QD for 2 weeks	N/A
ciclopirox (Loprox®)	Gel: apply TOP BID to affected area Shampoo: apply ~5 to 10 mL to wet hair, lather and leave on for ~3 min. Repeat BIW for 4 weeks.	N/A
selenium sulfide	Lotion: massage ~5 to 10 mL into wet scalp. Leave on for 2 to 3 min, then rinse scalp. Repeat application for a total of 2 applications each week for 2 weeks. Shampoo: massage shampoo into wet scalp and then rinse thoroughly at least BIW.	N/A

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information
The various trial durations are supported by treatment guidelines and clinical trials for each indication.

V. References

1. Sumadan Prescribing Information. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc. March 2013. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bd6d3adc-0852-4425-aabb-b8bb62f4a34f. Accessed October 13, 2017.
2. Goldgar C, Keahey DJ, Houchins J. Treatment options for Acne Rosacea. American Family Physician. 2009 Sept Jan; 80(5):461-468.
3. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10.31.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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