



Louisiana

Topical Acne Products

Policy # 00343

Original Effective Date: 02/20/2013

Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With "Step Therapy" (generic before brand) ONLY:

Based on review of available data, the Company may consider brand name topical acne products including, but not limited to products containing dapsone (e.g., Aczone[®] and branded dapsone 7.5% gel)[†], azelaic acid (e.g., Azelex[®])[‡], benzoyl peroxide (e.g., Zoderm[®], Benziq[®])[‡], sulfacetamide (e.g., Klaron[®])[‡], sulfacetamide/sulfur (e.g., Avar[®], Zetacet[®])[‡], clindamycin (e.g., Cleocin-T[®], Clindagel[®], Clindets[®], Evoclin[®], branded clindamycin phosphate)[‡], minocycline (e.g., Amzeeq[™])[‡], closcaterone (Winlevi[®])[‡], and combinations of these products (e.g., Benzamycin PAK[®], Inova[®], Aktipak[™], Epiduo[®])[‡] to be **eligible for coverage**** when the patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name topical acne products when ALL of the specific drug's criteria are met:

- Patient has tried and failed one generic prescription topical adapalene, benzoyl peroxide, clindamycin, erythromycin, dapsone, or sodium sulfacetamide containing product; OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name topical acne products when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

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Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

For Patients With "Prior Authorization" ONLY:

Based on review of available data, the Company may consider Aktipak (erythromycin/benzoyl peroxide), Azelex (azelaic acid), the branded clindamycin products Clindagel, Cleocin-T, and Evoclin, Amzeeq (minocycline foam), or Winlevi (clocaterone) to be **eligible for coverage**** when the patient selection criteria for the requested drug are met:

Patient Selection Criteria

Coverage eligibility will be considered for Aktipak (erythromycin/benzoyl peroxide), Azelex (azelaic acid), branded clindamycin products (Clindagel, Cleocin-T, Evoclin, and branded clindamycin phosphate), Amzeeq (minocycline foam), or Winlevi (clocaterone) when the following criteria are met:

- For Aktipak Requests ONLY:
 - Drug will be used for topical treatment of acne vulgaris; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) an over the counter benzoyl peroxide product for at least one month unless there is clinical evidence or patient history that suggests the use of this product will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient has tried and failed (e.g., intolerance or inadequate response) a separate benzoyl peroxide product AND generic topical clindamycin or erythromycin product used together for at least one month unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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- Patient has tried and failed (e.g., intolerance or inadequate response) generic combination erythromycin-benzoyl peroxide gel or generic combination clindamycin-benzoyl peroxide gel for at least one month unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Cleocin-T, Clindagel, Evoclin, or branded clindamycin phosphate requests ONLY:
 - Patient is 12 years of age or older; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient has a diagnosis of acne vulgaris; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g. benzoyl peroxide); AND
 - All covered topical clindamycin products (e.g. generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g. generic topical erythromycin solution); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*
 - Requested drug will not be used in combination with erythromycin-containing products.
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Azelex requests ONLY:
 - Patient is 12 years of age or older; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient has a diagnosis of mild to moderate inflammatory acne vulgaris; AND

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- Patient has tried and failed (e.g. intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g., benzoyl peroxide); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND
 - All covered topical clindamycin products (e.g., generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g., generic topical erythromycin solution).

*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Amzeeq requests ONLY:
 - Patient is 9 years of age or older; AND
 - Patient has a diagnosis of inflammatory lesions of non-nodular moderate to severe acne vulgaris; AND
 - Patient has tried and failed (e.g. intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g. benzoyl peroxide); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND
 - All covered topical clindamycin products (e.g. generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g. generic topical erythromycin solution).

*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*
- For Winlevi requests ONLY:
 - Patient is 12 years of age or older; AND
 - Patient has a diagnosis of acne vulgaris; AND

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- Patient has tried and failed (e.g., intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g. benzoyl peroxide); AND
 - All covered topical clindamycin products (e.g. generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g. generic topical erythromycin solution); AND
 - All covered generic topical adapalene, tretinoin, and tazarotene products.

*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Aktipak (erythromycin/benzoyl peroxide) when the patient has not tried and failed an over the counter benzoyl peroxide product for at least one month AND a separate benzoyl peroxide product and generic topical clindamycin or erythromycin product used together for at least one month AND a generic combination erythromycin/benzoyl peroxide gel or generic combination clindamycin/benzoyl peroxide gel for at least one month to be **not medically necessary.****

Based on review of available data, the Company considers the use of brand clindamycin products when the patient is younger than 12 years of age, is not unable to use the available generic products listed above or is using the clindamycin product in combination with an erythromycin-containing product to be **not medically necessary.****

Based on review of available data, the Company considers the use of Azelex (azelaic acid) when the patient is younger than 12 years of age or is not unable to use the available generic products listed above to be **not medically necessary.****

Based on review of available data, the Company considers the use of Amzeeq (minocycline foam) or Winlevi (closoaterone) when the patient is not unable to use the available generic products listed above to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Aktipak (erythromycin/benzoyl peroxide), Winlevi (clocaterone), or brand clindamycin products for any indication other than for the treatment of acne vulgaris to be **investigational**.*

Based on review of available data, the Company considers the use of Azelex (azelaic acid) for any indication other than the treatment of mild to moderate acne vulgaris to be **investigational**.*

Based on review of available data, the Company considers the use of Amzeeq (minocycline foam) for any indication other than non-nodular, moderate to severe acne vulgaris in patients 9 years of age or older to be **investigational**.*

Based on review of available data, the Company considers the use of Winlevi (clocaterone) in patients younger than 12 years of age to be **investigational**.*

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With BOTH "Prior Authorization" AND "Step Therapy":

Based on review of available data, the Company may consider brand name topical acne products including, but not limited to products containing dapsone (e.g., Aczone[®] and branded dapsone 7.5% gel), azelaic acid (e.g., Azelex), benzoyl peroxide (e.g., Zoderm, Benziq), sulfacetamide (e.g., Klaron), sulfacetamide/sulfur (e.g., Avar, Zetacet), clindamycin (e.g., Clindagel, Cleocin-T, Clindets, Evoclin, branded clindamycin phosphate), minocycline (e.g., Amzeeq), clocaterone (Winlevi), and combinations of these products (e.g., Benzamycin PAK, Inova, Aktipak, Epiduo) to be **eligible for coverage**** when the patient selection criteria are met:

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Patient Selection Criteria

Coverage eligibility will be considered for brand name topical acne products when ALL of the specific drug's criteria are met for the requested drug:

- For Aktipak requests ONLY:
 - Drug will be used for topical treatment of acne vulgaris; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) an over the counter benzoyl peroxide product for at least one month unless there is clinical evidence or patient history that suggests the use of this product will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) a separate benzoyl peroxide product AND generic topical clindamycin or erythromycin product used together for at least one month unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) generic combination erythromycin-benzoyl peroxide gel or generic combination clindamycin-benzoyl peroxide gel for at least one month unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
- For Cleocin-T, Clindagel, Evoclin, or branded clindamycin phosphate requests:
 - Patient is 12 years of age or older; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient has a diagnosis of acne vulgaris; AND
 - Patient is unable to use ALL of the following topical acne products due to either inadequate response, hypersensitivity, or intolerance:
 - ONE topical over the counter acne product (e.g., benzoyl peroxide); AND
 - All covered topical clindamycin products (e.g., generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g., generic topical erythromycin solution); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND

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- Requested drug will not be used in combination with erythromycin-containing products
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Azelex requests ONLY:
 - Patient is 12 years of age or older; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient has a diagnosis of mild to moderate inflammatory acne vulgaris; AND
 - Patient has tried and failed (e.g. intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g., benzoyl peroxide); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND
 - All covered topical clindamycin products (e.g., generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g., generic topical erythromycin solution).*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Amzeeq requests ONLY:
 - Patient is 9 years of age or older; AND
 - Patient has a diagnosis of inflammatory lesions of non-nodular moderate to severe acne vulgaris; AND
 - Patient has tried and failed (e.g. intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g. benzoyl peroxide); AND
 - All covered topical adapalene, topical tretinoin, or topical tazarotene products; AND

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- All covered topical clindamycin products (e.g. generic topical clindamycin solution, foam, gel, and lotion); AND
- All covered topical erythromycin or topical sulfacetamide products (e.g. generic topical erythromycin solution).

*(Note: These patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

- For Winlevi requests ONLY:
 - Patient is 12 years of age or older; AND
 - Patient has a diagnosis of acne vulgaris; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) ALL of the following topical acne products unless there is clinical evidence or patient history that suggests the alternative treatments will be ineffective or cause an adverse reaction to the patient:
 - ONE topical over the counter acne product (e.g. benzoyl peroxide); AND
 - All covered topical clindamycin products (e.g. generic topical clindamycin solution, foam, gel, and lotion); AND
 - All covered topical erythromycin or topical sulfacetamide products (e.g. generic topical erythromycin solution); AND
 - All covered generic topical adapalene, tretinoin, and tazarotene products.
- For all other brand name topical acne product requests:
 - Patient has tried and failed one generic prescription topical adapalene, benzoyl peroxide, clindamycin, erythromycin, dapsone, or sodium sulfacetamide containing product; OR
 - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

*(Note: The criteria requiring the trial and failure of other products are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Aktipak (erythromycin/benzoyl peroxide) when the patient has not tried and failed an over the counter benzoyl peroxide product for at least one month AND a separate benzoyl peroxide product and generic topical clindamycin or erythromycin product used together for at least one month AND a generic combination erythromycin/benzoyl peroxide gel or generic combination clindamycin/benzoyl peroxide gel for at least one month to be **not medically necessary.****

Based on review of available data, the Company considers the use of brand clindamycin products when the patient is younger than 12 years of age, is not unable to use the available generic products listed above or is using the clindamycin product in combination with an erythromycin-containing product to be **not medically necessary.****

Based on review of available data, the Company considers the use of Azelex (azelaic acid) when the patient is younger than 12 years of age or is not unable to use the available generic products listed above to be **not medically necessary.****

Based on review of available data, the Company considers the use of Amzeeq (minocycline foam) or Winlevi (closocterone) when the patient is not unable to use the available generic products listed above to be **not medically necessary.****

Based on review of available data, the Company considers the use of brand name topical acne products (other than Aktipak, Azelex, Amzeeq, Winlevi, or brand clindamycin products) when the patient has NOT tried and failed one generic prescription topical adapalene, benzoyl peroxide, clindamycin, erythromycin, or sodium sulfacetamide containing product OR when there is no documentation of clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Aktipak (erythromycin/benzoyl peroxide), Winlevi (closocterone), or branded clindamycin products for any indication other than for the treatment of acne vulgaris to be **investigational**.*

Based on review of available data, the Company considers the use of Winlevi (closocterone) in patients younger than 12 years of age to be **investigational**.*

Based on review of available data, the Company considers the use of Azelex (azelaic acid) for any indication other than the treatment of mild to moderate acne vulgaris to be **investigational**.*

Based on review of available data, the Company considers the use of Amzeeq (minocycline foam) for any indication other than non-nodular, moderate to severe acne vulgaris in patients 9 years of age or older to be **investigational**.*

Background/Overview

Many topical acne products are available for the treatment of acne vulgaris. Benzoyl peroxide containing products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris. Adapalene products are indicated for the treatment of acne. Azelaic acid is indicated for the topical treatment of mild to moderate inflammatory acne vulgaris and for the treatment of inflammatory pustules and papules of mild to moderate acne rosacea. Topical clindamycin, erythromycin, and dapsone gel are indicated for the treatment of acne vulgaris. Amzeeq (minocycline foam) is indicated for the topical treatment of moderate to severe acne vulgaris in patients 9 years of age or older. Sulfacetamide sodium and sulfur are antimicrobial and antiseptic agents which aid in the removal of keratin and drying of the skin. Closocterone is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients greater than or equal to 12 years of age. Guidelines do not prefer any of the specific brand name agents over their generically similar products for the treatment of acne.

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For topical acne medications to be effective, they must be applied as directed in order to prevent the formation of new lesions. Thus, these agents should be used daily on areas of the skin prone to acne and maintenance therapy is needed to prevent recurrence.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name topical acne product over the available generic topical acne products. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

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Policy History

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02/07/2013 Medical Policy Committee review

02/20/2013 Medical Policy Implementation Committee approval. New policy.

02/06/2014 Medical Policy Committee review

02/19/2014 Medical Policy Implementation Committee approval. No change to coverage.

03/05/2015 Medical Policy Committee review

03/20/2015 Medical Policy Implementation Committee approval. No change to coverage.

03/03/2016 Medical Policy Committee review

03/16/2016 Medical Policy Implementation Committee approval. Added generic adapalene as a step 1 product.

03/02/2017 Medical Policy Committee review

03/15/2017 Medical Policy Implementation Committee approval. Removed generic erythromycin from step 1 as the brand erythromycin product is obsolete.

03/01/2018 Medical Policy Committee review

03/21/2018 Medical Policy Implementation Committee approval. Added erythromycin to step 1 because generic erythromycin product is now available; added Aktipak and Epiduo to step 2. Also separated out into step, step/PA, and PA only to address the PA added to Aktipak. Updated background and rationale.

09/06/2018 Medical Policy Committee review

09/19/2018 Medical Policy Implementation Committee approval. Added PA criteria for Cleocin T, Clindagel, and Evoclin.

06/06/2019 Medical Policy Committee review

06/19/2019 Medical Policy Implementation Committee approval. Added new clindamycin product.

02/06/2020 Medical Policy Committee review

02/12/2020 Medical Policy Implementation Committee approval. Added new dapsone product to step therapy section and added new drug, Amzeeq, with PA criteria. Also added generic dapsone to step 1.

10/01/2020 Medical Policy Committee review

10/07/2020 Medical Policy Implementation Committee approval. Added prior authorization criteria for Azelex.

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04/01/2021 Medical Policy Committee review

04/14/2021 Medical Policy Implementation Committee approval. Added new drug, Winlevi, to policy with relevant criteria and background information. Added generic topical tazarotene as an additional option to try and fail in PA criteria for topical clindamycin, Azelex, and Amzeeq.

Next Scheduled Review Date: 04/2022

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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Louisiana

Topical Acne Products

Policy # 00343

Original Effective Date: 02/20/2013

Current Effective Date: 05/10/2021

- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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