Guideline note 21: Severe Inflammatory Skin Disease*

Lines 424,480,502,530,539,654

Inflammatory skin conditions included in this guideline are:

a. Psoriasis
b. Atopic dermatitis
c. Lichen planus
d. Darier disease
e. Pityriasis rubra pilaris
f. Discoid lupus

The conditions above are included on line 424 if severe, defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following:

- At least 10% of body surface area involved; and/or
- Hand, foot or mucous membrane involvement.

The conditions above are included on line 480, 502, 530, 539, or 654 if mild, defined as uncomplicated, having:

- No functional impairment; and/or,
- Involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes.

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first line agents include topical corticosteroids, narrowband UVB, cyclosporine, methotrexate, and azathioprine. Second line agents include topical pimecrolimus and topical tacrolimus and should be limited to those who fail or have contraindications to first line agents.

*Subject to change with updates to the guideline note, most current guideline note to always be referenced

Topical Corticosteroids

Formulary Medication	Dosage form	Restriction
High potency topical corticosteroids		
Betamethasone dipropionate, augmented	0.05% cream and ointment	No restriction
Betamethasone dipropionate, augmented	0.05% lotion	PA required
Betamethasone dipropionate	0.05% ointment	PA required
Clobetasol propionate	0.05% cream, gel, ointment, solution	No restriction
Clobetasol propionate	0.05% foam, lotion, shampoo	PA required
Fluocinonide	0.05% cream, gel, ointment and topical solution	PA required
Triamcinolone acetonide	0.5% cream and ointment	No restriction
Intermediate potency topical corticosteroid		
Betamethasone dipropionate	0.05% cream, lotion	PA required
Betamethasone valerate	0.1% ointment, cream	PA required
Mometasone furoate	0.1% cream, ointment and lotion	PA required
Triamcinolone acetonide	0.1%, 0.25%, 0.5% cream	No restriction
Triamcinolone acetonide	0.1% lotion	PA required
Low Potency topical corticosteroids		
Hydrocortisone	0.5%, 1% and 2.5% cream, lotion, and ointment 1% topical solution	No restriction

1) Is the requested medication for an OHP funded condition?
   Note: Review for relevant comorbid conditions or exceptional need
   a. If Yes, Move to question #2
   b. If No, Category 1 denial

2) Is the requested medication appropriate given the intended area to treat (i.e. lotion, solutions, foams and shampoos are appropriate for the scalp, high potency steroids not appropriate for use on the face, etc.)?
   a. If Yes, Move to question #3
   b. If No, Category 5 denial.

3) Is the request for a formulary medication?
   a. Approve for up to 12 months
   b. If No, Move to question #4.

4) Has the member tried and failed appropriate formulary options?
   a. If Yes, approve for up to 12 months
   b. If No, Category 15 denial.

Vitamin D analog

Formulary Medication	Dosage form	Restriction
Calcipotriene	0.005% cream, ointment, topical solution	PA required

1. Is the diagnosis being treated for OHP funded plaque psoriasis defined as severe per Guideline Note 21?
   Note: Review for relevant comorbid conditions or exceptional need
   a. If Yes, Move to question #2.
   b. If No, Category 1 denial.

2. Has the member tried and been adherent to prior therapy with an appropriate topical corticosteroid?
   a. If Yes, Move to question #3.
   b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

3. Is the requested medication on formulary (calcipotriene)?
   a. If Yes, Move to question #5.
   b. If No, Move the question #4.

4. Has the member tried and failed or has adverse reaction to formulary calcipotriene?
   a. If Yes, Move to question #5.
   b. If No, Category 15 denial.

5. Is this medication a new start for member?
   a. If Yes, Approve as Amended for 3 month trial
   b. If No, Move to question #6.

6. Does provided documentation demonstrate efficacy and tolerability of treatment for member's symptoms?
   a. If Yes, approved for up to 12 months of therapy.
   b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

Topical Retinoids

Formulary Medication	Dosage Form	Restrictions
Adapalene	0.1% cream and gel, 0.3% gel	PA required
Tazarotene (Tazorac)	0.05%, 0.1% cream and gel	PA required
Tretinoin	0.025%, 0.5%, 0.1% cream 0.01% and 0.025% gel	PA required

1. Is the member being treated for an OHP funded condition plaque psoriasis or Darier Disease defined as severe per Guideline note 21?

Note: Review for relevant comorbid conditions or exceptional need

a. If Yes, Move to Question #2
b. If No, Category 1 denial.

2. Is the member being treated for Darier Disease?
   a. If Yes, Move to Question #5
   b. If No, Move to Question #3

3. Is the member being treated for severe Plaque-type psoriasis?
   a. If Yes, Move to Question #4
   b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) review.

4. Has the member tried and been adherent to prior combination therapy with an appropriate topical corticosteroid and vitamin D analog for at least 8 consecutive weeks?
   a. If Yes, Move to question #5
   b. If No, Forward to Medical Director for medical appropriateness (Category 5) evaluation.

   **Exceptions may be made at the discretion of the MD for hyperkeratotic lesions that meet the comorbid rule for funding*.

5. Is female member on a long-acting or permanent form of contraception?
   If member is male, move to question #7.
   a. If Yes, Move to question #7
   b. If No, Move to Question #6

6. Is female member using 2 forms of contraception (as noted in clinical documentation and review of MedAccess for medication adherence if appropriate).
   a. If Yes, Move to question #7
   b. If No, Forward to Medical Director for medical appropriateness (Category 5) evaluation

   **Exceptions may be made at the discretion of reviewing MD if use of Tazorac is intended for limited BSA*

7. Is this medication a new start for member?
   a. If Yes, approve as amended for 3 month trial
   b. If No, Approve for up to 12 weeks with documented evidence of efficacy, tolerability and adherence to therapy.

Topical Calcineurin Inhibitors

Formulary Medication	Dosage Form	Restrictions
Tacrolimus	0.03%, 0.1% ointment	PA required

1. Is the member being treated for intertriginous or facial psoriasis or atopic dermatitis defined as severe per guideline note 21?
   a. If Yes, Move to question #2.
   b. If No, Category 1 denial.

2. Does the member have a diagnosis of severe psoriasis?
    a. If Yes, Move to question #4
    b. If No, Move to question #3

3. Does the member have a diagnosis of severe atopic dermatitis?
    a. If Yes, Move to question #5
    b. If No, Category 3 denial

4. Has the member tried and been adherent to prior therapy with an appropriate topical corticosteroid, Tazorac or phototherapy?
    a. If Yes, Move to question #6
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

5. Has the member tried and been adherent to prior, first line therapy:

Must have trial of all of the following	Must have trial of two of the following
Review and elimination of potential exacerbating factors (exposure to solvents, detergents, overheating of the skin, etc.)	Methotrexate
Appropriate topical corticosteroid	Cyclosporine
Narrowband UVB phototherapy	Azathioprine

    a. If Yes, move to question #6
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

6. Is the member over the age of 2 years of age and immunocompetent?
    a. If Yes, Move to question #7
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation or category 3 denial.

7. Is the request for formulary topical tacrolimus?
    a. If Yes, approve as amended authorization for 3 month trial (new starts)
    b. If Yes, approve for up to 12 months for continuation of therapy with demonstrated efficacy, tolerability and adherence to prescribed regimen
    c. If No, Move to question #8.

8. Has the member tried and failed or have contraindication to formulary topical tacrolimus?
    a. If Yes, approve as amended authorization for 3 month trial (new starts)
    b. If Yes, approve for up to 12 months for continuation of therapy with demonstrated efficacy, tolerability and adherence to prescribed regimen
    c. If No, Category 15 denial.

Soriatane (acitretin)

1. Is the diagnosis being treated for OHP funded condition?
    a. If Yes, Move to question #2.
    b. If No, Category 1 denial.

2. Is the medication being prescribed by or in consultation with a dermatologist or rheumatologist?
    a. If Yes, Move to question #3
    b. If No, Forward to pharmacist Medical Director for medical appropriateness (Category 5) evaluation.

3. Is female member currently pregnant as confirmed by a negative pregnancy prior to initiation of therapy? ***If male member proceed to question #7***
    a. If No, move to question #4
    b. If Yes, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

4. Does member agree to avoid pregnancy for 3 years following discontinuation of therapy?
    a. If Yes, Move to question #5
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

5. Is female member on a long acting or permanent form of contraception?
    a. If Yes, Move to Question #7
    b. If No, Move to Question #6

6. Is female member effective using 2 forms of contraception (as noted in clinical documentation and review of MedAccess for medication adherence if appropriate).
    a. If Yes, Move to question #7
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation
    Rational: Retinoid Acid Derivatives are highly teratogenic. Package insert recommends two forms of contraception to prevent pregnancy.

7. Does the documentation demonstrate that the provider is adherent to REMS criteria associated with prescribed medication (including documentation of negative pregnancy test and plan for monthly pregnancy test throughout therapy if appropriate)?
    a. If Yes, Move to question #8
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

8. Is the member being treated for severe plaque psoriasis as defined by Guideline note 21?
    a. If Yes, Move to question #9
    b. If No, Move to question #10

9. Has the member tried and been adherent to prior therapy with an appropriate topical corticosteroid combined with a vitamin D analog, methotrexate, and phototherapy?
    a. If Yes, Move to question #11

b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

**Exceptions may be made at the discretion of reviewing MD for palmer/plantar psoriasis*

10. Does the member have a diagnosis of any of the following conditions
    - Severe Pityriasis Rubra Pilaris
    - Severe Lichen Planus with previous trial of first line agents such as topical corticosteroids, phototherapy, or second line preferred formulary glucocorticoids (recommended dose 30-60mg daily for 4-6 weeks followed by a taper with medication discontinuation after 4-6 weeks)
    - Severe Darier Disease with adequate trial of general protective measures (keeping skin cool, regular use of moisturizers containing keratolytics, and antiseptic washes), topical corticosteroids, topical retinoids (tazarotene), and tacrolimus.

    a. If Yes, Move to question #11.
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

11. Is this medication a new start for member?
    a. If Yes, approve as amended for 3 month trial.
    b. If No, See continuation of therapy PA criteria.

Continuation of therapy Criteria

1. Does provided documentation demonstrate efficacy and tolerability of treatment for member's symptoms?
    a. If Yes, Move to question #2.
    b. If No, Forward to Medical Director for medical appropriateness (Category 5) evaluation.

2. Is member male or a female member on a long acting or permanent form of contraception?
    a. If Yes, Approved for 12 months of therapy
    b. If No, Move to Question #3

3. Is female member using 2 forms of contraception (as noted in clinical documentation and review of MedAccess for medication adherence if appropriate).
    a. If Yes, Approve in three month intervals.
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

Biologics for the treatment of Severe Inflammatory Skin Disease

Tumor Necrosis Factor alpha Inhibitors (Adalimumab, Etanercept, Infliximab)

New Start Criteria

1. Is the member being treated for an OHP funded condition of severe plaque psoriasis as defined by guideline note 21?
    a. If Yes, Move to question #2
    b. If No, Category 1 denial

2. Is the medication prescribed by, or in consultation with, a dermatologist or rheumatologist?
    a. If Yes, Move to question #3
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

3. Does the member have a history of recurring infections or an active infection?
    a. If No, Move to question #4
    b. If Yes, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

4. Does the member have any of the following exclusions to therapy with a TNF-inhibitor?
    - Pregnant or breastfeeding
    - High risk of infection—uncontrolled diabetes, chronic leg ulcers, recurrent chest infections, indwelling urinary catheter
    - Multiple sclerosis
    - Active malignancy
    - Severe CHF

    a) If No, Move to question #5
    b) If Yes, Forward to pharmacist or Medical Director to evaluate for medical appropriateness

5. Has the member tried and failed (8 consecutive week trial), had documented adverse reaction or have contraindications to, ALL of the following
    - High potency topical corticosteroids used in combination with a vitamin D analogue
    - At least one other topical agent: tazarotene, tacrolimus, etc.

    Exceptions may be made for BSA greater than 20%--safety of tazarotene has not been established in psoriasis.
    - PUVA or UVB phototherapy
    - Methotrexate *(Exceptions may be made for pediatric members)*
    - At least one other second line systemic agent: acitretin

    a. If Yes, Move to question #6
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

6. Is the medication have a FDA indication for the condition being treated?
    a. If Yes, Move to question #7
    b. If No, Category 3 Denial

7. Is the medication being prescribed within FDA approved limits?
    a. If Yes, Approve for 6 month trial
    b. If No, Category 3 denial

Continuation of therapy

1. Is there demonstrated 80% or greater adherence to prescribed biologic and non-biologic regimen?
    a. If Yes, Move to question #2.

   b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

2. Has the member experienced a 50% reduction in plaques and/or is there evidence of functional improvement since starting therapy?
   a. If Yes, Approve for 1 year
   b. If No, Forward to Medical Director for medical appropriateness (Category 5) evaluation

Non-TNF inhibitor Biologic therapy for severe inflammatory skin disease

Secukinumab (Cosentyx)/brodalumab (Siliq)/Ixekizumab (Taltz)

New Start

1. Is the member being treated for an OHP funded condition of severe plaque psoriasis as defined by guideline note 21?
   a. If Yes, Move to question #2
   b. If No, Category 1 denial

2. Is the medication being prescribed by or in consultation with a dermatologist?
   a. If Yes, Move to question #3
   b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

3. Is the member over the age of 18 years old?
   a. If Yes, Move to question #4
   b. If No, Category 3 denial

4. Does the member have a history of recurring infections or an active infection?
   a. If No, Move to question #5
   b. If Yes, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

5. Has the member tried and failed (8 consecutive weeks), had adverse reaction to or have contraindications to, ALL of the following
   - High potency topical corticosteroids combined with vitamin D analogue
   - At least one other topical agent: tazarotene, tacrolimus, etc.

   Exceptions may be made for BSA greater than 20%--safety of tazarotene has not been established in psoriasis.
   - PUVA or UVB phototherapy
   - Methotrexate
   - At least one other second line systemic agent: acitretin, etc.

   a. If Yes, Move to question #6
   b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

6. Has the member tried and failed for have contraindication to Humira or infliximab used in combination with methotrexate?
   a. If Yes, Approve for 12 week trial (see dosing table 1 below for Cosentyx requests)

b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

Continuation of therapy

1. Is there demonstrated 80% or greater adherence to prescribed biologic and non-biologic regimen?
    a. If Yes, Move to question #2.
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

2. Has the member experienced a 50% improvement in affected body surface area, plaques severity and/or functioning since starting therapy?
    a. If Yes, approved for 12 months (Requests for Cosentyx requests see table 1 below)
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

Ustekinumab (Stelara)

New Start Criteria

1. Is the member being treated for an OHP funded condition of severe plaque psoriasis as defined by guideline note 21?
    a. If Yes, Move to question #2
    b. If No, Category 1 denial

2. Is the medication being prescribed by or in consultation with a dermatologist?
    a. If Yes, Move to question #3
    b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation

3. Does the member have a history of recurring infections or an active infection?
    a. If Yes, Move to question #4
    b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation

4. Has the member tried and failed (8 consecutive week trial), had documented adverse reaction or have contraindications to, ALL of the following
    - High potency topical corticosteroids combined with a vitamin D analogue
    - At least one other topical agent: tazarotene, tacrolimus

    Exceptions may be made for BSA greater than 20%--safety of tazarotene has not been established in psoriasis.
    - PUVA or UVB phototherapy
    - Methotrexate *(Exceptions may be made for pediatric members)*
    - At least one other second line systemic agent: acitretin, etc.

    a. If Yes, Move to question #5
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

5. Has the member tried and failed or have contraindication to Humira or infliximab used in combination with methotrexate?
    a. If Yes, Move to question #6.

b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

6. Has the member tried and failed or have a contraindication to Cosentyx, Siliq or Taltz (*minimum of 12 weeks of therapy will be considered an adequate trial*)?
    a. If Yes, Approve for 16 week trial (See dosing table 1 below)
    b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

Continuation of therapy

1. Is there demonstrated 80% or greater adherence to prescribed biologic and non-biologic regimen?
    a. If Yes, Move to question #2.
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

2. Has the member experienced a 50% improvement in affected body surface area, plaques severity and/or functioning since starting therapy?
    a. If Yes, approve for 12 months (see dosing table 1 below)
    b. If No, forward to Medical Director for medical appropriateness (Category 5) evaluation

Dupilumab (Dupixent)

1. Is the diagnosis being treated for OHP funded atopic dermatitis defined as severe per guideline note 21?
    a. If Yes, Move to question #2.
    b. If No, Category 1 denial.

2. Is the medication being prescribed by, or in consultation with, a dermatologist?
    a. If Yes, Move to question #3
    b. If No, forward to pharmacist or Medical Director for medical appropriateness (category 5) evaluation

3. Is the member 18 years of age or older?
    a. If Yes, Move to question #4
    b. If No, Category 3 denial.

4. Has the member tried and failed (with 80% or greater adherence) or have contraindication to first line therapy as defined in guideline note 21:

Must have trial of all of the following	Must have trial of two of the following
Review and elimination of potential exacerbating factors (exposure to solvents, detergents, overheating of the skin, etc.)	Methotrexate
Appropriate topical corticosteroid	Cyclosporine
Narrowband UVB phototherapy	Azathioprine

a. If Yes, move to question #5
b. If No, Forward to pharmacist or Medical Director for medical appropriates (Category 5) evaluation.

5. Has the member tried and failed (8 week trial with 80% or greater adherence) or have contraindication to second line agents for the treatment of atopic dermatitis as defined in guideline note 21?
   - Topical tacrolimus (formulary)
   a. If Yes, approve for 16 week trial.
   b. If No, Forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation

Continuation of therapy

1. Is there demonstrated 80% or greater adherence to prescribed biologic and non-biologic regimen?
   a. If Yes, Move to question #2.
   b. If No, forward to pharmacist or Medical Director for medical appropriateness (Category 5) evaluation.

2. Has the member experienced a 50% reduction eczema area and severity from baseline and/or is there evidence of functional improvement since the start of treatment?
   a. If Yes, Approved for 12 months
   b. If No, Forward to Medical Director for medical appropriateness (Category 5) evaluation

Cosentyx	Induction	Maintenance dosing
00078-0639-41 (2 pack pens) 00078-0639-98 (2 pack syringes)		
Plaque Psoriasis	12 week trial authorize 300mg dosing NDC specific for 2 pack boxes Loading dose 300mg (week 0, 1, 2, 3, and 4)	**150mg monthly** Load override to allow processing of 2 pack every 56 days. If member fails trial at 150mg dose, may approve maintenance dosing of 300mg. Confirm NDC loaded is for 2 pen/syringe box
Psoriatic Arthritis	<u>Coexistent moderate to severe plaque psoriasis:</u> see plaque psoriasis induction schedule <u>Without coexistent moderate to severe plaque psoriasis:</u> No loading dose is required. See maintenance dosing schedule	**150mg monthly** Load override to allow processing of 2 pack every 56 days. If member fails trial at 150mg dose, may approve maintenance dosing of 300mg. Confirm NDC loaded is for 2 pen/syringe box

Stelara	
Plaque Psoriasis	All weights to start at 45mg dose

	Allowance of escalation of therapy to 90mg if there is no significant response to 45mg dose AND weight >100kg
Psoriatic Arthritis	All weights to start at 45mg dose Allowance of escalation of therapy to 90mg if there is no significant response to 45mg dose AND weight >100kg