Anti-Fungals – Topical Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

Drug(s) to be added to the therapeutic class:

- ciclopirox solution
- Jublia® (efinaconazole)
- tavaborole

Anti-Fungals – Topical

Drug	FDA Approved and Medicaid Covered Indications	Dosing	Availability	Mechanism of Action
ciclopirox solution	Topical treatment of mild to moderate onychomycosis of fingernails and toenails due to Trichophyton rubrum in patients 12 years and older.	Once daily (preferably at bedtime or 8 hours before washing) to all affected nails for 48 weeks; daily applications should be made over the previous coat and removed with alcohol every 7 days.	8% nail lacquer topical solution	Chelation of polyvalent cations (Fe+3 or Al+3)
efinaconazole (Julia®)	Topical treatment of onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophytes in patients 6 years and older.	Apply once daily for 48 weeks to the toenail, toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate using the integrated flow-through brush applicator.	10% solution	Azole antifungal
tavaborole	Topical treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes	Apply to affected toenails once daily for 48 weeks. Should be applied to the entire toenail surface and under the tip of each toenail being treated.	5% solution	Azole antifungal

Ciclodan solution [package insert]. South Plainfield, NJ; Medimetriks; October 2019.
Julia [package insert]. Bridgewater, NJ; Bausch; March 2022.
Kerydin [package insert]. New York, NY; Pfizer; August 2018

Anti-Fungals – Topical

Drug	Contraindications	Warnings and Precautions	Most Common Adverse Reactions
ciclopirox solution	Hypersensitivity to any components	Not for ophthalmic, oral, or intravaginal use. For use on nails and immediately adjacent skin only. If a reaction suggesting sensitivity or chemical irritation should occur with the use, treatment should be discontinued and appropriate therapy instituted. The risk of removal of the unattached, infected nail by the health care professional and trimming by the patient should be carefully considered before prescribing to patients with a history of insulin dependent diabetes mellitus or diabetic neuropathy.	Rash-related adverse events: periungual erythema and erythema of the proximal nail fold.
efinaconazole (Jublia®)	None	For topical use only. Not for oral, ophthalmic, or intravaginal use.	(incidence >1%) were ingrown toenails, application site dermatitis, application site vesicles, and application site pain.
tavaborole	None	For topical use only. Not for oral, ophthalmic, or intravaginal use.	≥1% included application site exfoliation, ingrown toenail, application site erythema, and application site dermatitis.

Ciclodan solution [package insert]. South Plainfield, NJ; Medimetriks; October 2019.
Jublia [package insert]. Bridgewater, NJ; Bausch; March 2022.
Kerydin [package insert]. New York, NY; Pfizer; August 2018

Anti-Fungals – Topical

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
V. Dermatologic Agents		
Anti-Fungals – Topical		
ciclopirox cream, suspension, shampoo clotrimazole OTC clotrimazole Rx clotrimazole/betamethasone cream ketoconazole cream ketoconazole 2% shampoo miconazole OTC nystatin cream, ointment, powder nystatin/triamcinolone terbinafine OTC tolnaftate OTC	Alevazol OTC butenafine (gen Mentax®) Ciclodan® cream ciclopirox gel clotrimazole/betamethasone lotion econazole Ertaczo® Extina® ketoconazole foam Loprox® shampoo luliconazole Luzu® Mentax® miconazole/zinc/petrolatum (gen Vusion®) F/Q/D naftifine Naftin® oxiconazole Oxistat® Vusion® F/Q/D	**FREQUENCY/QUANTITY/DURATION (F/Q/D)** **Vusion® 50 gm ointment** –Maximum 100 grams in a 90-day time period

Anti-Fungals – Topical

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Anti-Fungals, Topical – for Onychomycosis • ciclopirox 8% solution • efinaconazole (Jublia®) • tavaborole (Kerydin®)	• Trial with an oral antifungal agent* prior to use of ciclopirox 8% solution *terbinafine (Lamisil®) tablets; griseofulvin (Gris PEG®) oral suspension, ultramicronized tablets micronized tablets; itraconazole (Sporanox®,) tablets, oral solution • Trial with ciclopirox 8% solution prior to the use of other topical antifungals [efinaconazole (Jublia®) or tavaborole (Kerydin®)]		

Immunomodulators – Topical Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

Drug(s) to be added to the therapeutic class:

- Eucrisa® (crisaborole)
- Opzelura® (ruxolitinib)

Immunomodulators – Topical

Drug	FDA Approved and Medicaid Covered Indications	Dosing	Availability	Mechanism of Action
pimecrolimus (Elidel®)	Second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children ≥ 2 years of age, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable	Adults and children ≥ 2 years of age: apply a thin layer to affected skin twice daily	Cream: 30 g, 60 g, and 100 g tubes	Calcineurin inhibitor immunosuppressant
tacrolimus (Protopic®)	Second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable • 0.03% ointment approved for patients 2 years to 15 years old • 0.03% ointment and 0.1% ointment approved for adults	tacrolimus 0.03% (Protopic): Adults and children ≥ 2 years of age: apply a thin layer to affected skin twice daily tacrolimus 0.1% (Protopic): Adults: Apply a thin layer to affected skin twice daily	Ointment: 30 g, 60 g, and 100 g tubes	Calcineurin inhibitor immunosuppressant
crisaborole (Eucrisa®)	Topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients ≥ 3 months of age	Adults and children ≥ 3 months of age: apply a thin layer to affected skin twice daily	Ointment: 60 g, 100 g tubes	Phosphodiesterase 4 inhibitor
ruxolitinib (Opzelura®)	Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Use in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.	Adults and children ≥ 12 years of age: apply a thin layer twice daily to affected areas of up to 20% body surface area; do not use more than 60 grams per week, or one 100 gram tube per 2 weeks.	Cream: 60 g, 100 g tubes	Janus kinase (JAK) inhibitor

Eucrisa [package insert]. New York, NY; Pfizer; April 2023.
Elidel [package insert]. Bridgewater, NJ; Bausch; September 2020.
Protopic [package insert]. Madison, NJ; Leo; February 2019.
Opzelura [package insert]. Wilmington, DE; Incyte; September 2023.

Immunomodulators – Topical

Drug	Contraindications	Warnings and Precautions	Most Common Adverse Reactions
pimecrolimus (Elidel®)	History of hypersensitivity to pimecrolimus or any of the components of the cream.	Should not be used in immunocompromised adults and children, including patients on systemic immunosuppressive medications. Avoid treatment on malignant or pre-malignant skin conditions, as these can present as dermatitis. Should not be used in patients with Netherton's Syndrome or skin diseases with a potential for increased systemic absorption.	The most commonly reported adverse reactions (≥1%) were application site burning, headache, nasopharyngitis, cough, influenza, pyrexia, and viral infection.
tacrolimus (Protopic®)	History of hypersensitivity to tacrolimus or any other component of the ointment.	Long term safety has not been established. Should not be used in immunocompromised adults and children. Precautions: Avoid on pre-malignant and malignant skin conditions, bacterial and viral skin infections, and in patients with lymphadenopathy, sun exposure, immunocompromised status, or renal insufficiency.	The most common adverse events include skin burning and pruritus.
crisaborole (Eucrisa®)	Known hypersensitivity to crisaborole or any component of the formulation.	Hypersensitivity reactions: If signs and symptoms of hypersensitivity occur, discontinue immediately and initiate appropriate therapy.	The most common adverse reaction occurring in ≥1% in subjects is application site pain.
ruxolitinib (Opzelura®)	None.	• Serious Infections: Serious bacterial, mycobacterial, fungal and viral infections have occurred. Regularly monitor patients for infection and manage it promptly. • Non-melanoma Skin Cancers. Basal cell and squamous cell carcinoma have occurred. Perform periodic skin examinations during treatment and following treatment as appropriate. • Thrombosis: Thromboembolic events have occurred. • Thrombocytopenia, Anemia, and Neutropenia: Thrombocytopenia, anemia, and neutropenia have occurred. Perform CBC monitoring as clinically indicated.	In atopic dermatitis, the most common adverse reactions (incidence ≥ 1%) are nasopharyngitis, diarrhea, bronchitis, ear infection, increased eosinophil count, urticaria, folliculitis, tonsillitis, and rhinorrhea.

Eucrisa [package insert]. New York, NY; Pfizer; April 2023.
Elidel [package insert]. Bridgewater, NJ; Bausch; September 2020.
Protopic [package insert]. Madison, NJ; Leo; February 2019.
Opzelura [package insert]. Wilmington, DE; Incyte; September 2023.

Immunomodulators – Topical

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
V. Dermatologic Agents		
Immunomodulators – Topical [CC]		
pimecrolimus tacrolimus	Elidel® Protopic®	**CLINICAL CRITERIA** • All prescriptions require prior authorization • Refills on prescriptions are allowed

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Atopic Dermatitis Agents • crisaborole (Eucrisa®) • ruxolitinib (Opzelura®)	• Trial with a medium or high potency prescription topical steroid within the last 3 months	**QUANTITY LIMITS:** • 100 gm/30 days (crisaborole) • 240 gm/30 days (ruxolitinib)	• Confirm diagnosis of FDA-approved or compendia-supported Medicaid covered indication • ruxolitinib: age 12 years +

Topical Immunomodulators: Review of Preferred Drug List Clinical Criteria

NYS Medicaid Drug Utilization Review Board
May 16, 2024

NEW YORK STATE | Department of Health | Office of Health Insurance Programs
SUNY The State University of New York

Topical Immunomodulators Approved for Atopic Dermatitis

Drug / Mechanism	FDA Indication(s)	Ages	Formulation / Dosage
Pimecrolimus (Elidel®) Calcineurin inhibitor	Second-line* therapy for short-term, non-continuous chronic treatment of **mild-to-moderate AD** in non-immunocompromised individuals	≥2 years	1% cream Apply a thin layer to affected skin twice daily; stop when S/S resolve; re-examine if S/S persist beyond 6 weeks
Tacrolimus (Protopic®) Calcineurin inhibitor	Second-line* therapy for short-term, non-continuous chronic treatment of **moderate-to-severe AD** in non-immunocompromised individuals	≥2 years	0.03% ointment for children aged 2 – 15 years 0.03% and 0.1% ointment for adults Apply a thin layer to affected skin twice daily; stop when S/S resolve; re-examine if S/S persist beyond 6 weeks
Crisaborole (Eucrisa®) PDE-4 inhibitor	Treatment of **mild-to-moderate AD**	≥3 months	2% ointment Apply a thin layer to affected skin twice daily; consider reducing to once daily when clinical effect is achieved
Ruxolitinib (Opzelura®)† JAK inhibitor	Short-term, non-continuous chronic treatment of **mild-to-moderate AD** in non-immunocompromised individuals not adequately controlled with other topical prescription treatments or when such treatments are not advisable	≥12 years	1.5% cream Apply a thin layer twice daily to affected skin, up to 20% BSA; max 60 g tube per week or 100 g tube per 2 weeks

AD=atopic dermatitis; BSA=body surface area; FDA=Food and Drug Administration; JAK=Janus kinase; PDE-4=phosphodiesterase-4; S/S=signs and symptoms
*Second-line is defined as disease not adequately controlled with other topical prescription treatments or when such treatments are not advisable
†Ruxolitinib cream is also FDA-approved for topical treatment of nonsegmental vitiligo, which is a non-covered use in NYS Medicaid

Elidel® package insert. Quebec, Canada: Bausch Health Companies, Inc.; September 2020.
Protopic® package insert. Dublin, Ireland: Leo Laboratories, Ltd.; June 2022.
Eucrisa® package insert. New York, NY: Pfizer, Inc.; January 2024.
Opzelura® package insert. Wilmington, DE: Incyte Corporation; September 2023.

Current Clinical Criteria

NYRx Preferred Drug List (PDL)

Dermatologic Agents		
Immunomodulators – Topical CC		
Preferred	**Non-Preferred**	**Prior Authorization/Coverage Parameters**
pimecrolimus tacrolimus	Elidel® Protopic®	**Clinical Criteria (CC):** • All prescriptions require prior authorization • Refills on prescriptions are allowed

NYRx Drug Utilization Review (DUR) Program

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameters
Atopic dermatitis agents • crisaborole (Eucrisa®) • ruxolitinib (Opzelura®)	• Trial with a medium or high potency prescription topical steroid within the last 3 months	**Quantity limits:** • 100 gm/30 days (crisaborole) • 240 gm/30 days (ruxolitinib)	• Confirm diagnosis of FDA-approved or compendia-supported Medicaid covered indication • ruxolitinib: age 12 years +

Source: NYS Medicaid Fee-For-Service Preferred Drug List; revised March 20, 2024. Available at: https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf

Clinical Guidance

- American Academy of Dermatology (AAD):
  - 2023 guidelines for the management of atopic dermatitis (AD) with topical therapies in adults
  - Objective: to provide evidence-based recommendations for topical therapies available and approved in the United States (US) to standardize care and improve patient outcomes
  - Systematic review and Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach
  - Strength of recommendations
    - Strong recommendation for or against intervention = benefits clearly outweigh risk and burdens or vice versa; recommendation applies to most patients in most circumstances
    - Conditional recommendation for or against intervention = benefits are closely balanced with risk and burden or vice versa; recommendation applies to most patients, but most appropriate action may differ depending on patient or other stakeholder values
  - Certainty of evidence
    - High = very confident that the true effect lies close to that of the estimate of effect
    - Moderate = moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
    - Low = confidence in the effect estimate is limited; true effect may be substantially different
    - Very low = estimate of effect is very uncertain; true effect may be substantially different

Sidbury et al. *J Am Acad Dermatol*. 2023;89(1):e1-e20.

AAD-Recommended Topical Therapies for Adults with AD

Topical Therapies	Strength of Recommendation	Certainty of Evidence
Non-prescription therapies		
• Moisturizers	Strong	Moderate
Topical calcineurin inhibitors		
• Tacrolimus 0.03% or 0.1% ointment • Pimecrolimus 1% cream for mild-to-moderate AD	Strong Strong	High High
Topical corticosteroids		
• Topical corticosteroids, in general • Medium potency agents for intermittent use as maintenance therapy (twice weekly) to reduce disease flares and relapse	Strong Strong	High High
Topical PDE-4 inhibitors		
• Crisaborole ointment for mild-to-moderate AD	Strong	High
Topical JAK inhibitors		
• Ruxolitinib cream for mild-to-moderate AD	Strong	Moderate

AAD=American Academy of Dermatology; AD=atopic dermatitis; JAK=Janus Kinase; PDE=phosphodiesterase

Sidbury et al. *J Am Acad Dermatol*. 2023; 89(1):e1-e20.

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

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Clinical Guidance

- American Academy of Allergy, Asthma, and Immunology (AAAAI) / American College of Allergy, Asthma, and Immunology (ACAAI) Joint Task Force on Practice Parameters (JTFPP):[1]
  - 2023 GRADE- and Institute of Medicine-based AD guidelines
  - Objective: To produce evidence-based guidelines that support patients, clinicians, and other decision-makers in the optimal treatment of AD; includes topical and systemic therapies for children and adults
  - Systematic review and network meta-analysis of randomized trials provided evidence for evaluating topical therapies[2]
  - Therapies rated by strength of recommendation and certainty of evidence
    - Strong recommendations = “recommended for” or “recommended against”
    - Conditional recommendations = “suggested for” or “suggested against”

1. Chu et al. *Ann Allergy Asthma Immunol.* 2024;132:274−312.
2. Chu et al. *J Allergy Clin Immunol*. 2023; 152(6):1493-1519.

AAAAI / ACAAI JTFPP Interpretation of Strong vs Conditional Recommendations

Implications for	Strong Recommendation	Conditional Recommendation
Patients	Most would want the recommended course of action and only a small proportion would not.	Most would want the suggested course of action, but many would not. Decision aids may be useful to help patients make decisions based on their risks, values, and preferences.
Clinicians	Most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values or preferences.	Different choices will be appropriate for individual patients; clinicians must help each patient arrive at a management decision consistent with their values and preferences…
Policymakers	The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policy making will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision making is appropriate.
Researchers	The recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation…	The recommendation is likely to be strengthened (for future updates or adaptation) by additional research…

Excerpted from Table 2 in Chu et al. *Ann Allergy Asthma Immunol.* 2024;132:274−312.

AAAAI / ACAAI JTFPP AD Guidelines

Clinicians managing all severities of AD should address the following before issuing any new therapy:

- Diagnosis
  - Ensure correct diagnosis and identify any complicating diagnoses
- Education
  - Inform about disease, skin care, and action plan
- Triggers
  - Address trigger avoidance
- Adherence
  - Ensure proper medication use/adherence
- Moisturizer
  - Encourage use of a bland moisturizer at least once daily

Chu et al. *Ann Allergy Asthma Immunol.* 2024;132:274−312.

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

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AAAAI / ACAAI JTFPP Guidelines for Topical AD Therapies

Severity of dermatitis	Recommendation	Strength	Certainty
Prescription (Rx) moisturizers			
Mild/Moderate/Severe	Suggest against using Rx moisturizer rather than fragrance-free over-the-counter moisturizer	Conditional against	Low
Topical corticosteroids (TCS)			
Mild/Moderate/Severe	Recommend adding TCS if refractory to moisturizers	Strong in favor	High
Topical calcineurin inhibitors (TCI)			
Mild/Moderate/Severe	Recommend adding TCI if refractory to moisturizers	Strong in favor	High
Topical PDE-4 inhibitors			
Mild/Moderate	Suggest adding crisaborole if refractory to moisturizers	Conditional in favor	Moderate
Topical JAK inhibitors			
Mild/Moderate	Suggest against adding ruxolitinib if refractory to moisturizers	Conditional against	Low

Adapted from Figure 1. Chu et al. *Ann Allergy Asthma Immunol.* 2024;132:274−312.

Comparator State Medicaid Programs

- Preferred drug list criteria were searched/reviewed for 9 comparator state programs:
  - California, Colorado, Florida, Illinois, Massachusetts, Michigan, Pennsylvania, Texas, Washington
  - The topical immunomodulators were not listed in the California Contract Drugs List
  - Pennsylvania PDL was not accessible online as of 4/22/24
- Drug placement on the PDL varies by state
- Prior authorization criteria include some or all of the following:
  - FDA-indicated age and diagnosis, disease severity, non-immunocompromised status, consultation with a specialist, failure with a trial of 1 or more other topical prescription agents

California Department of Health Care Services. Medi-Cal Formulary. Available at https://medi-calrx.dhcs.ca.gov/home/cdl/. Accessed April 11, 2024; Colorado Department of Health Care Policy and Financing. Health First Colorado Pharmacy Benefit. Available at https://hcpf.colorado.gov/medicaid-pharmacy-benefits. Accessed April 11, 2024; Florida Agency for Health Care Administration. Florida Medicaid Drug Criteria. Available at https://ahca.myflorida.com/medicaid/prescribed_drug/drug_criteria.shtml. Accessed April 11, 2024; Illinois Department of Healthcare and Family Services. Medicaid Preferred Drug List. Available at https://www2.illinois.gov/hfs/MedicalProviders/Pharmacy/preferred/Pages/default.aspx. Accessed April 11, 2024; Commonwealth of Massachusetts MassHealth Drug Utilization Review Program. Available at https://mhdl.pharmacy.services.conduent.com/MHDL/. Accessed April 11, 2024; Michigan Department of Health and Human Services. Medicaid Health Plan Pharmacy Benefit. Available at https://www.michigan.gov/mdhhs/0,5885,7-339-71547_4860-380454--,00.html. Accessed April 11, 2024; Pennsylvania Department of Human Services. Statewide Preferred Drug List. Available at https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Preferred-Drug-List.aspx. Access attempted April 11-22, 2024; Texas Medicaid & Healthcare Partnership. Formulary search. Available at https://www.txvendordrug.com/formulary/prior-authorization/preferred-drugs. Accessed April 11, 2024; Washington State Health Care Authority. Apple Health (Medicaid) Preferred Drug List. Available at https://www.hca.wa.gov/billers-providers-partners/programs-and-services/apple-health-preferred-drug-list-pdl. Accessed April 11, 2024.

Summary

- Four topical immunomodulators are FDA approved for treatment of AD
  - Pimecrolimus and tacrolimus, both TCI, for ages ≥2 years
  - Crisaborole, a PDE-4 inhibitor, for ages ≥3 months
  - Ruxolitinib, a JAK inhibitor, for ages ≥12 years
- Recently updated evidence-based guidelines provide fairly consistent clinical guidance on use of topical therapies
  - Topical corticosteroids (TCS) and TCI are strongly recommended for treating mild, moderate, or severe AD that is uncontrolled with daily use of moisturizers
  - Crisaborole is strongly or conditionally recommended as an alternative to TCS or TCI for mild-moderate AD uncontrolled with moisturizers
  - Ruxolitinib recommendations are mixed due to short-term safety and efficacy data and concern for risks associated with systemic absorption

Recommendations

- For streamlining and consistency with evidence-based guidelines, consider updating the NYRx PDL clinical criteria for topical immunomodulators as follows:
  - Include crisaborole and ruxolitinib with pimecrolimus and tacrolimus in the PDL topical immunomodulator section
  - Modify clinical criteria for pimecrolimus and tacrolimus to allow for use as an alternative to other topical prescription therapies
  - Remove step therapy and frequency/quantity/duration (F/Q/D) parameters for crisaborole
  - For ruxolitinib:
    - Modify step therapy parameters to require trial with a TCS, TCI, or crisaborole
    - Retain F/Q/D, diagnosis, and age parameters

Anabolic Steroids – Topical Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

Drug to be added to the therapeutic class:

- Natesto® (testosterone nasal gel)

Anabolic Steroids – Topical

Drug	FDA Approved Indications
testosterone gel (Androgel®)	Testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, such as primary or secondary hypogonadism (congenital or acquired)
testosterone gel (Fortesta®)	
testosterone gel (Testim®)	
testosterone gel (Vogelxo®)	
testosterone nasal gel (Natesto®)	
testosterone solution	
testosterone transdermal system (Androderm®)	

Anabolic Steroids – Topical

Drug	Dosing	Administration	Availability
testosterone 1% gel (Androgel 1%)	5 g daily, preferably in the morning (delivers 5 mg systemically); Dosing may be increased to 10 mg (by 2.5 mg increments)	Apply to clean, dry, intact skin of the shoulders and upper arms; Do not apply to the genitals	2.5 g, 5 g packets (contains 25 mg or 50 mg testosterone, respectively; 30 packets)
testosterone 1.62% gel (Androgel 1.62%)	40.5 mg (1.25 g of gel) once daily; Dosing may be adjusted between 20.25 mg and 81 mg based on levels drawn at 14 and 28 days after start of therapy	Apply to clean, dry, intact skin of the shoulders and upper arms; Do not apply to the genitals	1.25 g, 2.5 g packets (contains 20.25 mg or 40.5 mg testosterone, respectively; 30 packets); 75 g pump with 60 pump actuations delivering 20.25 mg of testosterone per actuation (1.25 g of gel)
testosterone gel (Fortesta)	Initiate at 40 mg once every morning; Dosing may be adjusted from 10 mg to 70 mg based on levels 2 hours after application at days 14 and 35 after start of last adjustment	Apply to clean, dry, intact skin of the front and inner thighs; Do not apply to genitals or other parts of the body	In a 60 g canister with metered dose pump delivering 10 mg testosterone in 0.5 g gel per actuation
testosterone 1% gel (Testim)	5 g daily, preferably in the morning (delivers 5 mg systemically)	Apply to clean, dry, intact skin of the shoulders and/or upper arms; Do not apply to genitals or abdomen	Tubes containing 50 mg testosterone in 5 g gel (30 per package)
testosterone gel (Vogelxo)	50 mg applied topically once daily at approximately the same time each day; Dosing may be adjusted to 100 mg once daily based on levels drawn at 14 days after start of therapy; Maximum dose is 100 mg daily	Apply to clean, dry, intact skin of the shoulders and/or upper arms; Do not apply to genitals or abdomen	In unit-dose tubes or packets containing 50 mg testosterone in 5 g of gel; Multiple-dose metered pumps delivering 12.5 mg of testosterone in 1.25 g of gel per actuation

Anabolic Steroids – Topical

Drug	Dosing	Administration	Availability
testosterone nasal gel (Natesto)	11 mg total, or 1 pump actuation in each nostril, 3 times a day (once in the morning, once in the afternoon, and once in the evening, about 6 to 8 hours apart); Maximum total daily dose is 33 mg intranasally	Patients should blow nose prior to administration; Actuator should be tipped toward lateral wall of nostril to ensure gel is applied appropriately prior to pressing the pump; Refrain from blowing nose or sniffing for 1 hour following administration; Do not apply to genitals or abdomen	Metered dose pump containing 11 g of gel dispensed as 60 metered pump actuations; each actuation delivers 5.5 mg of testosterone
testosterone solution	Initiate at 60 mg once a day; Dosing may be adjusted 30 mg based on levels drawn 2 to 8 hours after application at days 14 after start or last adjustment	Apply to clean, dry, intact skin of the axilla preferably at the same time every morning; Do not apply to the genitals or other parts of the body	110 mL of topical solution in a metered-dose pump; each pump delivers 30 mg of testosterone in 1.5 mL of solution; each bottle has an applicator top
testosterone transdermal (Androderm)	4 mg daily (nightly)	Apply to clean, dry skin of the back, abdomen, upper arms, or thighs; Do not apply to genitals, bony prominences, or parts of the body that may be subject to prolonged pressure due to sitting or sleeping; Rotate sites every 7 days	2 mg patches (60 per carton); 4 mg patches (30 per carton) Patches contain 9.7 mg testosterone (delivering 2 mg/day) or 19.5 mg (delivering 4 mg/day)

Anabolic Steroids – Topical

➢ Contraindications:

- All testosterone products carry a boxed warning on virilization of children following secondary exposure; the gel formulations also carry additional safety information regarding secondary exposure in women.
- Men with known carcinoma of the breast or known or suspected carcinoma of the prostate.
- Pregnant or breastfeeding women. Testosterone may cause fetal harm.

➢ Warnings and Precautions:

- Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone products. Evaluate patients with signs or symptoms consistent with DVT or PE.
- Some postmarketing studies have shown an increased risk of myocardial infarction and stroke associated with use of testosterone replacement therapy.
- Exogenous administration of androgens may lead to azoospermia.
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease.
- Sleep apnea may occur in those with risk factors.
- Monitor prostate specific antigen (PSA), hematocrit, and lipid concentrations periodically.

Anabolic Steroids – Topical

➢ Adverse Reactions:

- Application site reaction, headache, acne, hypertension, gynecomastia, increased hemoglobin/hematocrit
- Natesto nasal adverse effects include rhinorrhea, epistaxis, nasal discomfort, nasopharyngitis, bronchitis, upper respiratory tract infection, sinusitis, and nasal scab

➢ Special Populations:

- Safety and efficacy of testosterone products has not been established in pediatric patients less than 18 years of age. Improper use may result in acceleration of bone age and premature closure of epiphyses.
- Pregnancy Category X: contraindicated during pregnancy or in women who may become pregnant
- Contraindicated in nursing mothers
- Insufficient long-term safety data in geriatric patients
- No studies conducted in patients with renal or hepatic impairment

Anabolic Steroids – Topical

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Anabolic Steroids – Topical CDRP, F/Q/D		
testosterone gel testosterone pump	Androderm® AndroGel® pump Fortesta® Testim® Vogelxo	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • For diagnosis of hypogonadotropic or primary hypogonadism: – Requires documented low testosterone concentration with two tests prior to initiation of therapy. – Require documented testosterone therapeutic concentration to confirm response after initiation of therapy. • For diagnosis of delayed puberty: – Requires documentation that growth hormone deficiency has been ruled out prior to initiation of therapy. The Anabolic Steroid fax form can be found at: https://newyork.fhsc.com/downloads/providers/NYRx_CDRP_PA_Worksheet_Prescribers_Anabolic_Steroids.pdf For diagnosis of gender dysphoria, see Hormone Replacement Therapy for Treatment of Gender Dysphoria coverage in the DUR section of this document. **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Limitations for anabolic steroid products based on approved FDA labeled daily dosing and documented diagnosis: – Duration limit of 6 months for delayed puberty

Growth Hormones Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

New Clinical Information

- New Drug Entity: Ngenla™(Somatrogon-ghla)
- Discontinuation: Nutropin AQ® (somatropin)

Ngenla™(Somatrogon-ghla)

➢ Indications and Usage:

- NGENLA is a human growth hormone analog indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone

➢ Dosage and Administration:

- NGENLA treatment should be supervised by a healthcare provider who is experienced in the diagnosis and management of pediatric patients with growth hormone deficiency.
- Administer NGENLA by subcutaneous injection once weekly, on the same day each week, at any time of the day in the abdomen, thighs, buttocks, or upper arms with weekly rotation of injection site.
- The recommended dosage is 0.66 mg/kg based on actual body weight administered once weekly.
- Individualize dosage for each patient based on the growth response.
- Patients switching from daily growth hormone may initiate treatment with once-weekly NGENLA on the day following their last daily injection.
- If more than one injection is required to deliver a complete dose, each injection should be administered at a different injection site.

Ngenla [package insert]. New York, NY Pfizer; June 2023

Ngenla™ (Somatrogon-ghla)

➢ Dosage Forms and Strengths:

Injection:

- 24 mg/1.2 mL (20 mg/mL) single-patient-use prefilled pen that delivers a dose in 0.2 mg increments.
- 60 mg/1.2 mL (50 mg/mL) single-patient-use prefilled pen that delivers a dose in 0.5 mg increments.

➢ Contraindications:

- Acute critical illness
- Hypersensitivity to somatrogon-ghla or excipients
- Closed epiphyses
- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Prader-Willi syndrome who are severely obese or have severe respiratory impairment

Ngenla [package insert]. New York, NY Pfizer; June 2023

Ngenla™(Somatrogon-ghla)

➢ Warnings and Precautions:

- *Severe Hypersensitivity*: Severe hypersensitivity reactions may occur. In the event of an allergic reaction, seek prompt medical attention.
- *Increased Risk of Neoplasms*: Monitor patients with preexisting tumors for progression or recurrence. Increased risk of a second neoplasm in childhood cancer survivors treated with somatropin – in particular meningiomas in patients treated with radiation to the head for their first neoplasm .
- *Glucose Intolerance and Diabetes Mellitus*: NGENLA may decrease insulin sensitivity, particularly at higher doses. Monitor glucose levels periodically in all patients receiving NGENLA, especially in patients with existing diabetes mellitus or at risk for its development.
- *Intracranial Hypertension*: Perform fundoscopic examinations prior to initiation of treatment with NGENLA and periodically thereafter. If preexisting papilledema is identified, evaluate the etiology and treat the underlying cause before initiating. If papilledema occurs with NGENLA, stop treatment.
- *Fluid Retention*: May occur and may be dose dependent. Reduce dose as necessary.
- *Hypoadrenalism*: Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism.
- *Hypothyroidism*: Monitor thyroid function periodically as hypothyroidism may become evident or worsen after initiation with NGENLA.
- *Slipped Capital Femoral Epiphysis*: May develop. Evaluate patients with the onset of a limp or persistent hip or knee pain.
- *Progression of Preexisting Scoliosis*: Monitor for development or progression of scoliosis.
- *Pancreatitis*: Consider pancreatitis in patients with persistent severe abdominal pain.
- *Lipoatrophy*: May occur if NGENLA is administered in the same location over a long period of time. Rotate injection sites.

Ngenla [package insert]. New York, NY Pfizer; June 2023

Ngenla™(Somatrogon-ghla)

Adverse Reactions:

- Adverse reactions reported in ≥5% of patients treated with NGENLA are: injection site reactions, nasopharyngitis, headache, pyrexia, anemia, cough, vomiting, hypothyroidism, abdominal pain, rash, and oropharyngeal pain.

Drug Interactions:

- Replacement Glucocorticoid Treatment: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress dose following initiation of NGENLA.
- Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment: Adjust glucocorticoid dosing in pediatric patients to avoid both hypoadrenalism and an inhibitory effect on growth.
- Cytochrome P450-Metabolized Drugs: NGENLA may alter the clearance. Monitor carefully if used with NGENLA.
- Oral Estrogen: Larger doses of NGENLA may be required.
- Insulin and/or Other Antihyperglycemic Agents: Dose adjustment of insulin or antihyperglycemic agent may be required.

Specific Populations:

- Pregnancy: no available data on use in pregnant women to evaluate for a drug associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes
- Lactation: no data on the presence in human or animal milk, the effects on the breastfed infant, or the effects on milk production
- Females and Males of Reproductive Potential: Although somatrogon-ghla did not interfere with hCG pregnancy testing in a limited number of commercial tests, interference with hCG blood and urine pregnancy testing in patients receiving somatrogon-ghla may be possible, leading to either false positive or false negative results. Alternative methods (i.e., not reliant on hCG) are recommended to determine pregnancy.
- Pediatric use: safety and efficacy established in pediatrics 3 years of age and older
- Not studied in patients with hepatic or renal impairment

Ngenla [package insert]. New York, NY Pfizer; June 2023

Ngenla™(Somatrogon-ghla)

➢ Clinical Comparative Studies (within class):

- Pediatric Patients with Growth Hormone Deficiency (GHD)
  - A multi-center, randomized, open-label, active-controlled, parallel-group phase 3 study (NCT 02968004) was conducted in 224 treatment-naïve, prepubertal pediatric subjects with growth hormone deficiency (GHD).
  - The primary efficacy endpoint was annualized height velocity at Week 52.
  - Treatment with once-weekly NGENLA for 52 weeks resulted in an annualized height velocity of 10.1 cm/year. Patients treated with daily somatropin achieved an annualized height velocity of 9.8 cm/year after 52 weeks of treatment.

Ngenla [package insert]. New York, NY Pfizer; June 2023

Discontinuation

- **Nutropin AQ® (somatropin) injection**
  - Genentech reported the decision to discontinue commercial distribution of Nutropin AQ in the United States is a business decision, taken in view of the availability of generic and alternative treatments for patients, and is not related to any quality, safety or efficacy concerns with the product. Update posted on FDA website on 3/22/24.

https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Somatropin+Injection&st=d&tab=tabs-4&panels=0

Growth Hormones

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Growth Hormones CC, CDRP		
Genotropin® Norditropin®	Humatrope® Ngenla™ Nutropin AQ® Omnitrope® Saizen® Skytrofa® Sogroya® Zomacton®	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • Prescribers or their authorized agents may call or submit a fax request for a PA for beneficiaries 18 years of age or older **CLINICAL CRITERIA (CC)** • Patient-specific considerations for drug selection include concerns related to use of a non-preferred agent for FDA-approved indications that are not listed for a preferred agent. • Confirm diagnosis of FDA-approved or compendia-supported indication

Growth Hormone Agents: Review of Preferred Drug List Clinical Criteria

New York State Medicaid Drug Utilization Review Board
May 16, 2024

Current Clinical Criteria

- Growth hormone (GH) agents are in the Clinical Drug Review Program
- Reviewed in 2009, 2012, and 2021
- Clinical Criteria were implemented in 2021 requiring prior authorization in members ≥18 years of age:
  - Prescribers or their authorized agents may call or submit a fax for a prior authorization for members ≥18 years of age
  - Patient-specific considerations for drug selection include concerns related to use of a non-preferred agent for FDA-approved indications that are not listed for a preferred agent
  - Confirm diagnosis of FDA-approved or Compendia-supported indication
- Objective: determine whether Clinical Criteria should be implemented for all members using GH

NYSDOH DUR. Updated March 2024. Accessed April 11, 2024. https://www.health.ny.gov/health_care/medicaid/program/dur/.
New York State Department of Health. NYRx Medicaid program. Clinical Drug Review Program. Updated April 11, 2024. Accessed April 11, 2024. https://newyork.fhsc.com/providers/CDRP_PDP_classes_about.asp.

Drugs in the PDL Category

Preferred

- Genotropin® (somatropin)
- Norditropin® (somatropin)

Non-Preferred

- Humatrope® (somatropin)
- Ngenla™ (somatrogon-ghla)
- Nutropin AQ® (somatropin)
- Omnitrope® (somatropin)
- Saizen® (somatropin)
- Skytrofa® (lonapegsomatropin-tcgd)
- Sogroya® (somapacitan-beco)
- Zomacton® (somatropin)

New York State Medicaid Pharmacy Program Preferred Drug List. Updated March 20, 2024. Accessed April 11, 2024. https://newyork.fhsc.com/

FDA-Approved Indications

- Growth hormone deficiency (GHD) in pediatric and adult patients
- Chronic kidney disease (CKD) in pediatric patients
- Noonan syndrome (NS)
- Prader-Willi syndrome (PWS)
- Short stature homeobox-containing (SHOX) gene deficiency
- Small for gestational age (SGA)
- Turner syndrome (TS)
- Idiopathic short stature*

See end of slide presentation for product labeling references. Indications vary by GH agent.
**Idiopathic short stature is not a covered indication in NYRx.*

Clinical Guidelines - GHD

- American Association of Clinical Endocrinologists/American College of Endocrinology guidelines for GHD in **adult and transition patients** (2019) – diagnosis and monitoring:
  - Recommend use of GH stimulation tests in patients who have clinical characteristics suggestive of GHD (the number of GH stimulation tests is not specified)
  - Insulin-like growth factor (IGF-1) testing is also necessary for diagnosis of GHD and for monitoring of treatment response
    - IGF-1 levels and growth (transition patients only) should be measured 1 – 2 months following treatment initiation, then every 6 – 12 months thereafter

Yuen KCJ et al. *Endocr Pract*. Nov 2019;25(11):1191-1232. doi:10.4158/gl-2019-0405.

Clinical Guidelines - GHD

- Pediatric Endocrine Society guidelines for GHD in **pediatric patients** (2016) – diagnosis and monitoring:
  - Strongly recommend at least 2 different provocative tests be performed to diagnose GHD
  - Strongly recommend discontinuing GH treatment if the growth velocity is <2 – 2.5 cm/year
  - Serum IGF-1 levels should be monitored to assess for adherence and treatment response (frequency not addressed)

Grimberg A, et al. *Horm Res Paediatr*. 2016;86(6):361-397. doi:10.1159/000452150

Consensus Statements/Guidelines – CKD, PWS, SGA, and TS

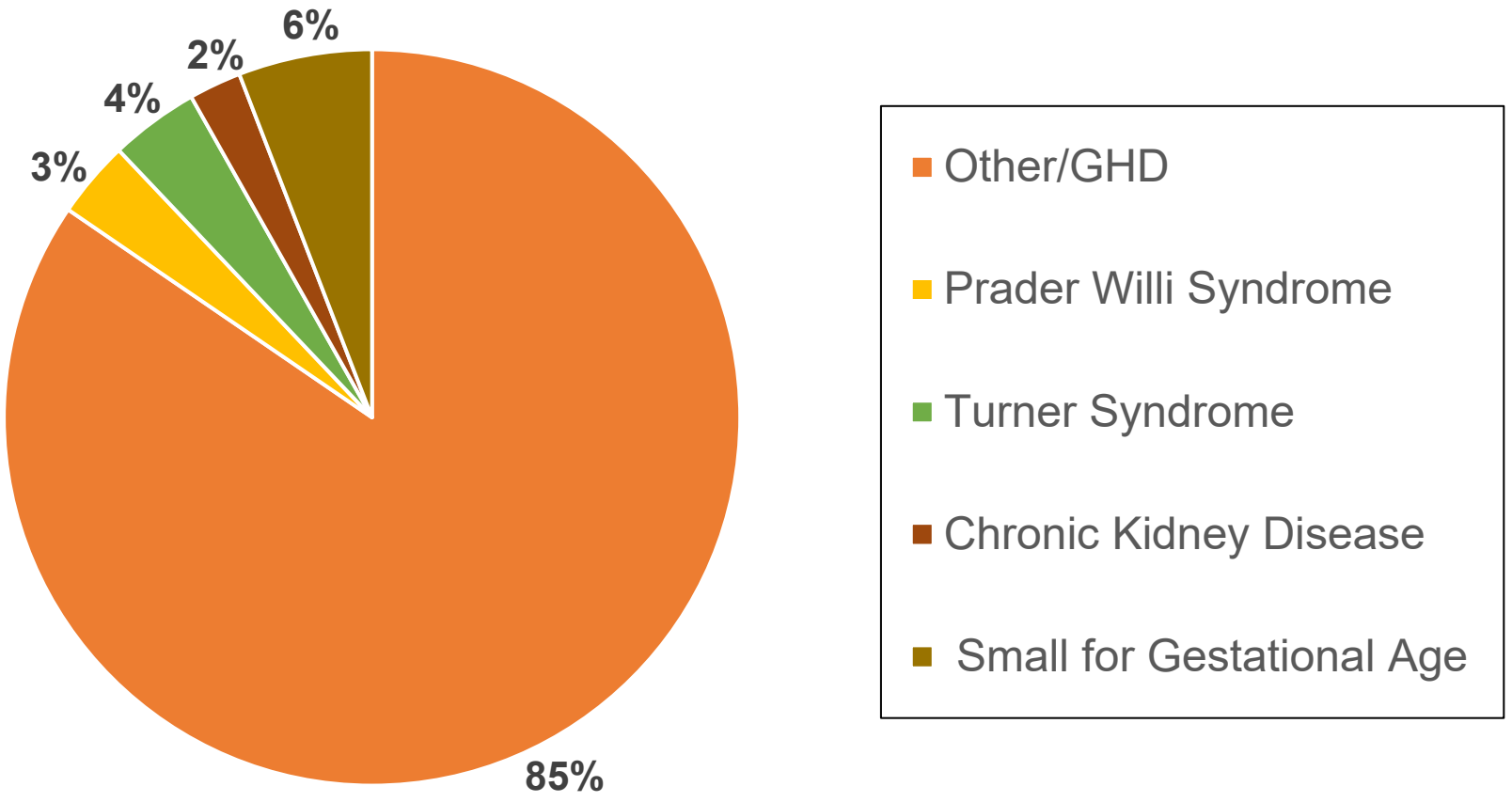
- Consensus statements/guidelines for CKD (2019), PWS (2013), SGA (2023), and TS (2016) – diagnosis and monitoring:
  - GH stimulation tests are not recommended (PWS-pediatric patients only, SGA) or addressed (CKD, TS)
  - Recommend that height be monitored: CKD/PWS (every 3 – 6 months) and SGA/TS (every 4 – 6 months in the first 6 months, then every 6 months thereafter)
  - Recommend that IGF-1 be monitored: CKD (annually), PWS (every 3 – 6 months), SGA (every 3 – 6 months, then annually), and TS (annually)
  - Treatment discontinuation is recommended if height velocity is <2 cm/year in CKD and <1 cm/6 months in SGA; treatment discontinuation not specifically addressed in PWS and TS

See end of slide presentation for references.

Clinical Guidelines

- No guidelines are available for Noonan syndrome and SHOX gene deficiency

Members Utilizing GH by Diagnosis (n=2,131)



GH=growth hormone; GHD=growth hormone deficiency.
Source=Medicaid Data Warehouse; ICD10 data: 4/1/21-3/31/23; extract date: 1/22/24.

Recommendations*

Consider implementing the following Clinical Criteria:

1. Confirm diagnosis of an FDA-approved or Compendia-supported indication for Medicaid-covered uses.
2. Documentation of recommended GHD diagnostic/laboratory test(s) prior to initiation of GH treatment in patients with GHD (e.g., provocative test and/or IGF-1 test).
3. Documentation of recommended GHD test annually for continuation of GH treatment in patients with GHD or SGA (e.g., IGF-1 test).
4. Documentation of treatment response for continuation of GH treatment in patients with GHD or SGA (e.g., annual growth velocity).

*Excludes patients with CKD, NS, PWS, SHOX, and TS.
*Excludes patients with all 3 of the following: auxological criteria, hypothalamic-pituitary defect, and deficiency of at least 1 other pituitary hormone.

References

1. New York State Department of Health. Drug Utilization Review. Updated October 2023. Accessed January 11, 2024. https://www.health.ny.gov/health_care/medicaid/program/dur/.
2. New York State Medicaid Pharmacy Program Preferred Drug List. Updated December 14, 2023. Accessed January 11, 2024. https://newyork.fhsc.com/
3. New York State Department of Health. NYRx Medicaid program. Clinical Drug Review Program. Updated January 11, 2024. Accessed January 11, 2024. https://newyork.fhsc.com/providers/CDRP_PDP_classes_about.asp
4. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. *Endocr Pract*. Nov 2019;25(11):1191-1232. doi:10.4158/gl-2019-0405
5. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-1 treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-1 deficiency. *Horm Res Paediatr*. 2016;86(6):361-397. doi:10.1159/000452150
6. Humatrope® [package insert]. Indianapolis, IN: Eli Lilly and Company; 2023.
7. Zomacton® [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; 2018.
8. Genotropin® [package insert]. New York, NY: Pharmacia & Upjohn Co.; 2019.
9. Ngenla™ [package insert]. New York, NY: Pfizer Inc.; 2023.
10. Norditropin® [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; 2020.
11. Omnitrope® [package insert]. Princeton, NJ: Sandoz, Inc.; 2019.
12. Saizen® [package insert]. Rockland, MA: EMD Serono; 2020.
13. Skytrofa® [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; 2022.
14. Sogroya® [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; 2023.
15. Nutropin AQ® [package insert]. South San Francisco, CA: Genentech, Inc.; 2016.

References

16. Deal CL, Tony M, Höybye C, Allen DB, Tauber M, Christiansen JS. Growth Hormone Research Society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader-Willi syndrome. *J Clin Endocrinol Metab*. Jun 2013;98(6):E1072-87. doi:10.1210/jc.2012-3888
17. Drube J, Wan M, Bonthuis M, et al. Clinical practice recommendations for growth hormone treatment in children with chronic kidney disease. *Nat Rev Nephrol*. Sep 2019;15(9):577-589. doi:10.1038/s41581-019-0161-4
18. Gravholt CH, Andersen NH, Conway GS, et al. Clinical practice guidelines for the care of girls and women with Turner syndrome: proceedings from the 2016 Cincinnati International Turner Syndrome Meeting. *Eur J Endocrinol*. Sep 2017;177(3):G1-g70. doi:10.1530/eje-17-0430
19. Hokken-Koelega ACS, van der Steen M, Boguszewski MCS, et al. International consensus guideline on small for gestational age: etiology and management from infancy to early adulthood. *Endocr Rev*. May 8 2023;44(3):539-565. doi:10.1210/endrev/bnad002

Hemophilia Agents – Factor VIII Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

Overview

- Hemophilia is a rare, inherited bleeding disorder where the blood does not clot properly due to an absence of 1 of the coagulation factors present in normal blood.
- Hemophilia is identified as an X-linked congenital bleeding disorder that has an estimated frequency of 1 in 5,000 male births.
- There are 2 main types of hemophilia, type A and type B.
- Patients with type A hemophilia exhibit low or missing levels of clotting factor VIII (8).
- Hemophilia A is also known as factor VIII deficiency, classical hemophilia, or standard hemophilia. Hemophilia A is far more common presenting in 80% to 85% of all hemophilia patients.
- Hemophilia A is classified as mild, moderate, or severe depending on the intrinsic amount of clotting factor VIII in the patient's blood.
- The National Hemophilia Foundation (NHF) Medical and Scientific Advisory Council (MASAC) published recommendations for the treatment of several forms of hemophilia, including hemophilia A, in 2022. MASAC states that recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A.

Mechanism of Action

- Factor VIII products are intravenously administered and designed to supplement endogenous coagulation factors in patients with hemophilia A.
- Products are differentiated based upon whether they are derived from pooled human plasma in the manufacturing process, as well as their level of purity or purification process.
- First generation product: Recombinate contains animal and/or human plasma-derived proteins in the cell culture medium, as well as in the final product formulation.
- Second generation products: Kogenate FS and Obizur are considered an advance over first generation products as they contain animal or human plasma in the medium but not in the final formulation vial.
- Third generation products: Adynovate, Advate, Afstyla, Eloctate, Esperoct, Jivi, Kovaltry, Novoeight, Nuwiq, and Xyntha do not contain any animal or human plasma-derived proteins in either the culture medium or final formulation.
- Esperoct is a glycopegylated form of recombinant anti-hemophilic factor, in which the factor VIII is conjugated to a polyethylene glycol (PEG) molecule thereby increasing the half-life and decreasing the clearance compared to the non-pegylated molecule.
- Xyntha is a B-domain deleted product that has the B-domain deleted from the factor VIII gene prior to its insertion into Chinese hamster ovary cells.
- Altuviiio is a von Willebrand factor (VWF) independent recombinant DNA-derived, factor VIII concentrate.

Hemophilia Agents – Factor VIII

Drug	FDA Approved and Medicaid Covered Indications
antihemophilic factor VIII – recombinant (Advate®)	• Control and prevention of bleeding episodes in adults and children with hemophilia A (classical hemophilia) • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for von Willebrand disease (vWD)
antihemophilic factor VIII – recombinant, PEGylated (Adynovate®)	• Control and prevention of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant, single chain (Afstyla®)	• Prevention and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (Altuviiio®)	• Prevention and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant, FC fusion protein (Eloctate®)	• Prevention and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis therapy to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD

Hemophilia Agents – Factor VIII

Drug	FDA Approved and Medicaid Covered Indications
antihemophilic factor – recombinant, glycopegylated exei (coagulation factor VIII concentrate) (Esperoct®)	• On-demand treatment and control of bleeding episodes in adults and children with hemophilia A • Perioperative management of bleeding in adults and children with hemophilia A • Routine prophylaxis to reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for the treatment of vWD
antihemophilic factor VIII – plasma derived (Hemofil M®)	• Control and prevention of hemorrhagic episodes in hemophilia A • Not indicated for vWD
antihemophilic factor VIII – plasma derived (Humate-P®)	• Treatment and prevention of bleeding in adults with hemophilia A • Treatment of spontaneous and trauma-induced bleeding episodes, and prevention of excessive bleeding during and after surgery for adults and pediatric patients with vWD; this applies to patients with severe and mild to moderate vWD where the use of desmopressin is known or suspected to be inadequate • Not indicated for the prophylaxis of spontaneous bleeding episodes in vWD
antihemophilic factor VIII – recombinant, PEGylated (Jivi®)	• Control and prevention of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia A • Perioperative management in adults and adolescents ≥ 12 years of age with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia A • Not indicated for use in previously untreated patients • Not indicated for vWD
antihemophilic factor VIII – plasma derived (Koate®)	• Control and prevention of bleeding episodes or in order to perform emergency and elective surgery on individuals with hemophilia A • Not approved for use in vWD
antihemophilic factor VIII – recombinant (Kogenate FS®)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children with hemophilia A and reduce the risk of joint damage in children showing no preexisting joint damage • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A • Not indicated for vWD

Hemophilia Agents – Factor VIII

Drug	FDA Approved and Medicaid Covered Indications
antihemophilic factor VIII – recombinant (Kovaltry®)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management of bleeds in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Novoeight®)	• On-demand treatment and control of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • Routine prophylaxis to reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Nuwiq®)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative bleed management in adults and children with hemophilia A • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant, porcine sequence (Obizur®)	• For the on-demand treatment and control of bleeding episodes in adults with acquired hemophilia A • Safety and efficacy have not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU • Not indicated for the treatment of congenital hemophilia A or vWD
antihemophilic factor VIII – recombinant (Recombinate®)	• Control and prevention of hemorrhagic episodes in hemophilia A in adults and children • Perioperative management in patients with hemophilia A • Not indicated for vWD
antihemophilic factor VIII – recombinant (Xyntha®, Xyntha® Solofuse)	• Control and prevention of bleeding episodes in adults and children with hemophilia A • Perioperative management in adults and children with hemophilia A • For routine prophylaxis to reduce the frequency of bleeding episodes in adults and children with hemophilia A • Not indicated for vWD

Contraindications/Warnings

- Contraindications for factor VIII products are similar.
  - All contraindicated in patients who have known anaphylactic or severe hypersensitivity reactions to the components of each product or in patients who are known to have a normal coagulation mechanism.
  - Preliminary signs of allergic reactions, which may escalate to anaphylaxis, can include angioedema, chest tightness, hypotension, rash, nausea, vomiting, paresthesia, restlessness, wheezing, and dyspnea.
- Warnings for all factor products are nearly equivalent.
  - Initial treatment with all bleeding factor products should be performed under the supervision of a qualified healthcare professional experienced in the treatment of bleeding disorders.
  - Recommended monitoring of plasma factor activity levels following administration of factor products is by 1-stage clotting assay or a chromogenic substrate assay to confirm that adequate levels have been achieved and maintained, when clinically indicated.

Adverse Reactions

- All factor VIII - containing products, derived from pooled human plasma, carry a risk of transmitting infectious diseases. These risks have been attenuated by various purification methods employed in their manufacture. In general, for all these products, the benefits of these products outweigh the risks.
- The most significant adverse event that may occur for hemophilia A patients is the development of inhibitors, IgG antibodies, that neutralize clotting factors administered to control bleeding episodes.
  - With the development of products with a greater level of purification, the development of inhibitors to factor VIII factors is recognized as the most severe treatment-related complication in hemophilia.
  - More frequently encountered in persons with severe hemophilia in comparison to patients diagnosed with moderate or mild hemophilia regardless of phenotype.

Dosing

- There are 2 primary methodologies employed in factor replacement therapy. Mild to moderate hemophilia A may be treated with episodic or “on demand” treatment of bleeds.
- Severe hemophilia patients, particularly younger hemophilia patients, are recommended to begin prophylactic factor replacement therapy where individualized dosages are given on a scheduled basis.
- 2020 World Federation of Hemophilia (WFH) guidelines state the standard of care for all patients with severe hemophilia is prophylaxis with clotting factor concentrates (CFCs) or other hemostatic products to prevent bleeding; therapy should be initiated before 3 years of age to prevent musculoskeletal complications caused by recurrent joint or muscle bleeds. Furthermore, episodic or “on demand” clotting factor replacement therapy is no longer considered a long-term treatment option.
- Episodic dosing is also often based on physician preference considering the patient’s severity, location, and type of trauma. The goal of episodic treatment is to raise the factor level in the blood from 40% to 100% depending on the location and level of injury.
- General dosing information for hemophilia A is commonly included in the respective product labels. These recommendations are usually provided as a range or percentage based on factor VIII in the blood.
  - Percentages or range can vary for each individual due to hemorrhage types, different surgical procedures, the presence or absence of inhibitors, and acute treatment versus prophylactic therapy.
  - To assure optimal treatment outcomes, it is recommended that factor activity levels be monitored during replacement therapy.
  - Ultimately, dosing decisions should be under the direction of the physician treating the condition

Special Populations

- Advate, Alphanate, Eloctate, Humate-P, Kogenate FS, Novoeight, Obizur, Recombinate, and Xyntha all carry a pregnancy category designation C.
- Adynovate, Afstyla, Esperoct, Hemofil M, Jivi, Kovaltry, Nuwiq have no data indicating safety in pregnant women. These agents should only be used during pregnancy if clearly warranted.
- Dosing of factor products for elderly patients should be individualized.

Hemophilia Agents – Factor VIII

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VIII. Hematological Agents		
Hemophilia Agents – Factor VIII		
Advate® Adynovate® Afstyla® Eloctate® Esperoct® Hemofil® M Humate-P® Jivi® Koate® Kogenate® FS Kovaltry® Novoeight® Nuwiq® Obizur® Recombinate™ Xyntha® Xyntha® Solofuse	Altuviiio™	

References

1 Advate [package insert]. Lexington, MA; Baxalta; December 2018.
2 Adynovate [package insert]. Lexington, MA; Baxalta; June 2021.
3 Afstyla [package insert]. Kankakee, IL; CSL Behring; April 2021.
4 Alphanate [package insert]. Los Angeles, CA; Grifols Biologics; March 2021.
5 Eloctate [package insert]. Waltham, MA; Bioverativ; December 2020.
6 Esperoct [package insert]. Plainsboro, NJ; Novo Nordisk; September 2022.
7 Hemofil M [package insert]. Lexington, MA; Baxalta; June 2018.
8 Humate-P [package insert]. Kankakee, IL; CSL Behring; June 2020.
9 Jivi [package insert]. Whippany, NJ; Bayer; August 2018.
10 Koate [package insert]. Fort Lee, NJ; Kedrion Biopharma; January 2022.
11 Kogenate FS with vial adapter [package insert]. Whippany, NJ; Bayer; December 2019.
12 Kovaltry with vial adapter [package insert]. Whippany, NJ; Bayer; October 2021.
13 Novoeight [package insert]. Plainsboro, NJ; Novo Nordisk; July 2020.
14 Nuwiq [package insert]. Paramus, NJ; Octapharma; June 2021.
17 Obizur [package insert]. Lexington, MA; Baxalta; September 2021.
16 Recombinate [package insert]. Lexington, MA; Baxalta; June 2018.
17 Xyntha [package insert]. Philadelphia, PA; Wyeth; July 2022.
18 Xyntha Solofuse [package insert]. Philadelphia, PA; Wyeth; July 2022.
19 Altuviiio [package insert]. Waltham, MA; Bioverativ; February 2023.
20 Bleeding Disorders. National Heart, Lung, and Blood Institute (NHLBI). Updated March 24, 2022. Available at: https://www.nhlbi.nih.gov/healthtopics/hemophilia. Accessed September 17, 2022.
21 WFH Guidelines for the management of hemophilia – 3rd edition – 2020 (updated August 2020). Available at: https://wfh.org/education-and-elearning/.
22 The Hemophilia, von Willebrand Disease & Platelet Disorders Handbook. Available at: https://www.hog.org/handbook/. Accessed September 17, 2022.
23 MASAC (Medical and Scientific Advisory Council) Recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. MASAC Document #272. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-ScientificAdvisory-Council-MASAC/MASAC-Recommendations.
24 Pabinger-Fasching I. The story of a unique molecule in hemophilia A: Recombinant single-chain factor VIII. Thrombosis Research. 2016; 114(Suppl 3): S2-S4. DOI: 10.1016/S0049-3848(16)30414-5.
25 Peyvandi F, Mannucci P, Garagiola I, et al. A randomized trial of factor VIII and neutralizing antibodies in hemophilia A. New Engl J Med. 2016; 374 (21):2054-2064. DOI: 10.1056/NEJMoa1516437.
26 Hemophilia A. Updated April 2021. Available at: https://rarediseases.org/rare-diseases/hemophilia-a/. Accessed September 17, 2022.
27 CDC. What is hemophilia? Available at: https://www.cdc.gov/ncbddd/hemophilia/facts.html. Accessed April 14th, 2024.

Immunomodulators – Systemic Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

New Clinical Information

- New Drug Entity: Omvoh™(mirikizumab-mrkz), Velsipity™(etrasimod), Bimzelx® (bimekizumab-bkzx)
- New Drug Formulation: Entyvio® pen (vidolizumab)
- New Indications
- Key Label Revisions
- Practice Guideline Updates

Omvoh™(mirikizumab-mrkz)

➢ Indications and Usage:

- OMVOH is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults

➢ Dosage and Administration:

- Prior to Treatment Initiation
  - Evaluate patients for tuberculosis (TB) infection.
  - Obtain liver enzymes and bilirubin levels.
  - Complete all age-appropriate vaccinations according to current immunization guidelines.
- Recommended Dosage
  - The recommended induction dosage is 300 mg administered by intravenous infusion over at least 30 minutes at Weeks 0, 4, and 8. The recommended maintenance dosage is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter.

Omvoh [package insert]. Indianapolis, IN; Eli Lilly; April 2024.

Omvoh™(mirikizumab-mrkz)

➢ Dosage Forms and Strengths:

Injection: Intravenous Infusion

- Injection: 300 mg/15 mL (20 mg/mL) solution in a single-dose vial

Subcutaneous Injection:

- Injection: 100 mg/mL solution in a single-dose prefilled pen
- Injection: 100 mg/mL solution in a single-dose prefilled syringe

➢ Contraindications:

- History of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

➢ Warnings and Precautions:

- Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis and infusion-related reactions, have been reported. If a severe hypersensitivity reaction occurs, discontinue and initiate appropriate treatment.
- Infections: OMVOH may increase the risk of infection. Do not initiate treatment with OMVOH in patients with a clinically important active infection until the infection resolves or is adequately treated. If a serious infection develops, do not administer OMVOH until the infection resolves.
- Tuberculosis: Do not administer OMVOH to patients with active TB infection. Monitor patients receiving OMVOH for signs and symptoms of active TB during and after treatment.
- Hepatotoxicity: Drug-induced liver injury has been reported. Monitor liver enzymes and bilirubin levels at baseline and for at least 24 weeks of treatment and thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded.
- Immunizations: Avoid use of live vaccines.

Omvoh [package insert]. Indianapolis, IN; Eli Lilly; April 2024.

Omvoh™(mirikizumab-mrkz)

➢ Adverse Reactions:

Most common adverse reactions (≥2%) are:

- Induction: upper respiratory tract infections and arthralgia.
- Maintenance: upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection.

➢ Special Populations:

- Available data from case reports of mirikizumab-mrkz use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
- There are no data on the presence of mirikizumab-mrkz in human milk, the effects on the breastfed infant, or the effects on milk production.
- The safety and effectiveness of OMVOH have not been established in pediatric patients.
- No clinically meaningful differences in the pharmacokinetics of mirikizumab-mrkz were observed in subjects 65 years of age and older compared to younger adult subjects.

➢ Clinical Comparative Studies (within class):

- None

Omvoh [package insert]. Indianapolis, IN; Eli Lilly; April 2024.

Velsipity™ (etrasimod)

➢ Indications and Usage:

- VELSIPITY is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults.

➢ Dosage and Administration:

- Assessments are required prior to initiating VELSIPITY.
- The recommended dosage is 2 mg orally once daily.

➢ Dosage Forms and Strengths:

- Tablets: 2 mg of etrasimod

Velsipity [package insert]. New York, NY; Pfizer; October 2023.

Velsipity™ (etrasimod)

Contraindications:

- In the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure.
- History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Warnings and Precautions:

- Infections: May increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 5 weeks after discontinuation. Consider interruption of treatment if a serious infection develops. Avoid use of live attenuated vaccines during and for up to 5 weeks after treatment.
- Bradyarrhythmia and Atrioventricular Conduction Delays: May result in a transient decrease in heart rate and AV conduction delays. Obtain an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting treatment. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate.
- Liver Injury: Elevations of aminotransferases may occur. Obtain transaminase and bilirubin levels before initiating. Discontinue if significant liver injury is confirmed.
- Macular Edema: May increase the risk of macular edema. Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment. Periodically conduct an evaluation of the fundus, including the macula, while on therapy and any time there is a change in vision. Consider discontinuing if macular edema develops.
- Increased Blood Pressure: Monitor blood pressure during treatment.
- Fetal Risk: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for one week after stopping.
- Malignancies: Obtain a skin examination prior to or shortly after the start of treatment and periodically during treatment, especially if risk factors. Promptly evaluate suspicious skin lesions.
- Posterior Reversible Encephalopathy Syndrome (PRES): If symptoms develop, obtain a physical and neurological exam, and consider MRI.
- Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated.
- Unintended Additive Immune System Effects from Prior Treatment with Immunosuppressive or Immune-Modulating Drugs: Consider the half-life and mode of action of prior therapies.
- Immune System Effects After Stopping VELSIPITY: If using concomitant immunosuppressants, monitor patients for infectious complications for up to 5 weeks after the last dose.

Velsipity [package insert]. New York, NY; Pfizer; October 2023.

Velsipity™ (etrasimod)

Adverse Reactions:

- Most common adverse reactions (incidence ≥5%) are: headache, elevated liver tests, and dizziness.

Special Populations:

- Severe Hepatic Impairment: Use is not recommended
- Pregnancy: May cause fetal harm
- Increased exposure of etrasimod in patients who are CYP2C9 poor metabolizers is expected with concomitant use of moderate to strong inhibitors of CYP2C8 or CYP3A4. Concomitant use is not recommended in these patients.

Drug Interactions:

- Etrasimod is primarily metabolized by CYP2C8, CYP2C9, and CYP3A4. Table in package insert includes drugs with clinically important drug interactions when administered concomitantly with VELSIPITY and instructions for preventing or managing them. Consult the labeling of concomitantly used drugs to obtain further information.

Clinical Comparative Studies (within class):

- None

Velsipity [package insert]. New York, NY; Pfizer; October 2023.

Bimzelx® (bimekizumab-bkzx)

➢ Indications and Usage:

- BIMZELX is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis (PsA) in adults who are candidates for systemic therapy or phototherapy

➢ Dosage and Administration:

- Prior to treatment:
  - Evaluate patients for tuberculosis infection.
  - Test liver enzymes, alkaline phosphatase, and bilirubin.
  - Complete all age-appropriate vaccinations according to current immunization guidelines.
- Administer 320 mg (given as 2 subcutaneous [SC] injections of 160 mg each) at weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, a dosage of 320 mg every 4 weeks after week 16 may be considered.

➢ Dosage Forms and Strengths:

- Injection: 160 mg/mL in a single-dose prefilled syringe or single-dose prefilled autoinjector.

Bimzelx [package insert]. Smyrna, GA; UCB, Inc.; October 2023.

Bimzelx® (bimekizumab-bkzx)

Contraindications:

- None

Warnings and Precautions:

- Suicidal Ideation and Behavior: May increase risk.
- Infections: May increase risk of infection.
- Tuberculosis: Avoid use in patients with active TB. Initiate treatment of latent TB prior to Bimzelx treatment.
- Liver Biochemical Abnormalities: Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to patient management. Permanently discontinue use in patients with casually associated combined elevations of transaminases and bilirubin.
- Inflammatory Bowel Disease (IBD): Avoid use in patients with active IBD.

Adverse Reactions:

- Most common adverse reactions (incidence ≥1%) are upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Bimzelx [package insert]. Smyrna, GA; UCB, Inc.; October 2023.

Bimzelx® (bimekizumab-bkzx)

➢ Special Populations:

- Pregnancy: Insufficient data to evaluate for a drug associated risk of major birth defects, miscarriage, or other adverse maternal or feal outcomes.
- Lactation: There are no data in the presence in milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatrics: safety and effectiveness have not been established.

➢ Drug Interactions:

- The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, IFN) during chronic inflammation. Treatment with BIMZELX may modulate serum levels of some cytokines.
- Upon initiation or discontinuation of BIMZELX in patients who are receiving concomitant drugs which are CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) and consider dosage modification of the CYP450 substrate.

➢ Clinical Comparative Studies (within class):

- None

Bimzelx [package insert]. Smyrna, GA; UCB, Inc.; October 2023.

Entyvio® pen (vedolizumab)

➢ Indications and Usage:

ENTYVIO is an integrin receptor antagonist indicated in adults for the treatment of:

- moderately to severely active ulcerative colitis (UC).
- moderately to severely active Crohn's disease (CD).

➢ Dosage and Administration:

- Before initiating ENTYVIO, update immunizations according to current immunization guidelines
- Subcutaneous Injection: ENTYVIO prefilled syringe and ENTYVIO PEN are intended for subcutaneous use. A patient may self-inject or caregiver may inject after proper training on correct subcutaneous injection technique.
- Following the first two ENTYVIO intravenous doses administered at Week 0 and Week 2 in UC, ENTYVIO may be switched to subcutaneous injection at Week 6. Recommended subcutaneous dosage in UC starting at Week 6: 108 mg administered every 2 weeks.

➢ Dosage Forms and Strengths:

- Subcutaneous injection
  - Injection: 108 mg/0.68 mL solution in a single-dose prefilled syringe with needle safety device.
  - Injection: 108 mg/0.68 mL solution in a single-dose prefilled pen (ENTYVIO PEN).

Entyvio [package insert]. Lexington, MA; Takeda Pharmaceuticals, Inc..; September 2023.

Entyvio® pen (vedolizumab)

Contraindications:

- Patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Warnings and Precautions:

- Infusion-Related Reactions and Hypersensitivity Reactions: Discontinue ENTYVIO and initiate appropriate treatment if serious reactions occur.
- Infections: Treatment with ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. (5.2)
- Progressive Multifocal Leukoencephalopathy (PML): Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.

Adverse Reactions:

- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo) are: nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.
- Adverse reactions with subcutaneous ENTYVIO are similar to those reported with intravenous ENTYVIO with the exception of injection site reactions reported with subcutaneous ENTYVIO.

Entyvio [package insert]. Lexington, MA; Takeda Pharmaceuticals, Inc..; September 2023.

Entyvio® pen (vedolizumab)

Special Populations:

- Pregnancy: Have not reliably identified a drug associated risk or birth defects, miscarriage, or other adverse maternal or feal outcomes.
- Lactation: There is no data on the effects of vedolizumab on the breastfed infant, or the effects on milk production.
- Pediatrics: Safety and effectiveness have not been established.

Drug Interactions:

- Natalizumab Products: Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products.
- TNF Blockers: Because of the potential for increased risk of infections, avoid the concomitant use of ENTYVIO with TNF blockers.

Clinical Comparative Studies (within class):

- None

Entyvio [package insert]. Lexington, MA; Takeda Pharmaceuticals, Inc..; September 2023.

New Indications

- **Fasenra (benralizumab):**
  - Indication as add-on maintenance treatment of pts with severe asthma & with an eosinophilic phenotype has been expanded to include pediatrics aged 6 to 11 years old. Fasenra was previously approved for pts ≥ 12 years old for this indication

- **Xolair (omalizumab):**
  - FDA approved new indication for IgE-mediated food allergy in adult and peds pts ≥ 1 year old for reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods, used in conjunction with food allergen avoidance. Limitation of use stating not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

- **Dupixent (dupilumab):**
  - FDA approved expanded indication for treatment of eosinophilic esophagitis (EoE) to include peds ≥ 1 year old, weighing ≥ 15 kg. Previously, approved for treatment EoE in adult and peds pts ≥ 12 years old, weighing ≥ 40 kg.

- **Yuflyma (adalimumab-aaty):**
  - PI updated to include new indication of treatment of non-infectious intermediate, posterior, and panuveitis in adults.

- **Hyrimoz (adalimumab-adaz):**
  - FDA approved for treatment of non-infectious intermediate, posterior, & panuveitis in adults.

New Indications

- **Adbry (tralokinumab-ldrm):**
  - FDA expanded indication of moderate to severe atopic dermatitis to include pts ≥ 12 years old whose disease is not adequately controlled with topical Rx therapies or when those therapies are not advisable.
- **Cosentyx (secukinumab):**
  - FDA approved for treatment of adults with moderate to severe hidradenitis suppurativa (HS).
- **Idacio (adalimumab-aacf):**
  - FDA approved for treatment of non-infectious intermediate, posterior, & panuveitis in adults. FDA also approved for treatment of moderate to severe hidradenitis suppurativa (HS) in adults.
- **Orencia (abatacept):**
  - FDA has expanded SC use of Orencia for treatment of active psoriatic arthritis (PsA) to include pts ≥ 2 years old. Orencia had previously only been approved in adults for this indication.
- **Enbrel (etaneracept):**
  - FDA approved an expanded indication for PsA to include juvenile PsA (JPsA) in pts ≥ 2 years old.

New Indications

- **Rinvoq (upadacitinib):**
  - FDA expanded indication for treatment of active PsA and active polyarticular JIA (pJIA) in patients who have had an inadequate response or intolerance to ≥ 1 TNF blocker have both been expanded to include pts ≥ 2 years old. Rinvoq was previously only approved for adults for these indications.

- **Otezla (apremilast):**
  - FDA approved for treatment of pediatrics 6 to 17 years old weighing ≥ 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Otezla was previously only approved for treatment of plaque psoriasis in adults.

RA = Rheumatoid Arthritis, JIA = Juvenile Idiopathic Arthritis, PsA = Psoriatic Arthritis, AS = Ankylosing Spondylitis,
CD = Crohn's Disease, UC = Ulcerative Colitis, Ps or PsO = Psoriasis, HS = Hidradenitis Suppurativa, UV = Uveitis

Key Label Revisions

- Dupixent (dupilumab) - PI updated to remove the 100 mg dosage form. PI updates to Clinical Studies and Adverse Reactions sections with results from a study in atopic dermatitis with hand and/or foot involvement. PI updated with long-term safety data on treatment of adults with atopic dermatitis. Additional updates to pediatric use and geriatric use subsections.
- Ilumya (tildrakizumab-asmn) - PI updated with data from a clinical trial in patients with psoriasis of the scalp.
- Entyvio (vedolizumab) - Results from pregnancy exposure registry have been added to PI.
- Skyrizi (risankizumab-rzaa) - Preparation & administration instructions have been updated within Dosing section of PI to add 0.9% sodium chloride as a diluent for IV product. Pharmacokinetics section has been updated to add information on the lack of effect of risankizumab-rzaa on metabolism of several CYP substrates in patients with Crohn's Disease.
- Cibinqo (abrocitinib) - PI updated regarding recommended dosage with removal of 12-week time frame before increasing the dose and addition of recommendation to use lowest efficacious dose to maintain response. Pediatric Use subsection updated with removal of 25 kg weight limit. Clinical Studies section updated to include data from a new study.
- Cosentyx (secukinumab) - PI updated to include pyoderma gangrenosum as a postmarketing experience adverse drug reaction.

Key Label Revisions

- Yuflyma (adalimumab-aaty) - PI updated to be unbranded biological product labeling for adalimumab-aaty. Contains wording stating that the product is Yuflyma (a biosimilar to Humira). Addition of 2 starter packages for 40 mg/0.4 mL: Autoinjector (AI) Starter Package for PsO and AI Starter Package for CD, pediatric CD, UC, or HS.

- Idacio (adalimumab-aacf) - PI updated to be unbranded biological product labeling for adalimumab-aacf. Contains wording stating that the product is Idacio (a biosimilar to Humira).

- Abrilada (adalimumab-afzb) - Adalimumab-afzb (Abrilada) has been designated by the FDA as an interchangeable biosimilar to the corresponding presentations of adalimumab (Humira): 10 mg/0.2 mL & 20 mg/0.4 mL prefilled syringe for SC use; 40 mg/0.8 mL prefilled glass syringe, prefilled pen, & glass vial for SC use. This interchangeable designation applies to all indications: RA, JIA, PsA, AS, CD, UC, PsO, HS, & UV. Warnings & Precautions, Adverse Reactions, & Drug Interactions sections of PI updated to include additional data on use in HS & uveitis.

- Humira (adalimumab) - PI updated to introduce unbranded biological product labeling. Product is now referred to as "adalimumab" rather than "Humira" throughout PI.

RA = Rheumatoid Arthritis, JIA = Juvenile Idiopathic Arthritis, PsA = Psoriatic Arthritis, AS = Ankylosing Spondylitis,
CD = Crohn’s Disease, UC = Ulcerative Colitis, Ps or PsO = Psoriasis, HS = Hidradenitis Suppurativa, UV = Uveitis

Practice Guideline Updates

- **American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force published the 2023 guidelines (prior version 2012) on atopic dermatitis (AD).**

  Highlighted changes include the following recommendations or suggestions:

  - (1) recommendation for use of topical corticosteroids (TCS) or topical calcineurin inhibitors (TCIs) in pts with uncontrolled AD despite moisturizer use;
  - (2) suggestion for use of crisaborole 2% ointment for mild-to-moderate AD;
  - (3) suggestion against adding topical JAK inhibitors (e.g., ruxolitinib), for mild-to-moderate AD refractory to moisturizers alone;
  - (4) recommendation for proactive therapy with TCS or TCI for pts with a relapsing course;
  - (5) suggestion for allergen immunotherapy for moderate-to-severe AD;
  - (6) recommendation for dupilumab for pts ≥ 6 months of age or tralokinumab for pts ≥ 12 years, with moderate-to-severe AD refractory, intolerant, or unable to use midpotency topical treatment;
  - (7) suggestion for use of oral JAK inhibitors after evaluation of risks/benefits in adults and adolescents with moderate-severe AD refractory, intolerant, or unable to use mid- to high-potency topicals and systemic therapy (including a biologic as recommended previously);
  - (8) recommendation against use of baricitinib 1 mg and suggestion against use of azathioprine, methotrexate, and mycophenolate mofetil;
  - (9) suggestion for consideration of cyclosporine in adults and adolescents with moderate-severe AD refractory, intolerant, or unable to use mid- to high-potency topicals and biologics; and
  - (10) suggestion against use of systemic corticosteroids for AD.

https://www.annallergy.org/article/S1081-1206(23)01455-2/fulltext

Practice Guideline Updates

- **American Academy of Dermatology updated Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies (previously released in 2014)**
  - Give strong recommendation for monoclonal, antibodies dupilumab and tralokinumab, and JAK inhibitors, upadacitinib (after failure of other systemic therapies), abrocitinib (after failure of other systemic therapies), and off-label baricitinib; conditional recommendations are provided for systemic corticosteroids, and off-label use of methotrexate, mycophenolate mofetil, azathioprine, and cyclosporine.

https://www.jaad.org/action/showPdf?pii=S0190-9622%2823%2902878-5

Immunomodulators – Systemic

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Abrilada™ (adalimumab-AFZB) Actemra® subcutaneous adalimumab-AACF (gen Idacio®) adalimumab-FKJP (gen Hulio®) adalimumab-ADAZ (gen Hyrimoz®) adalimumab-ADBM (gen Cyltezo®) Adbry™ Amjevita™ Bimzelx® Cibinqo™ Cimzia® Cyltezo® (adalimumab-ADMB) Entyvio pen® Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® Ilumya® Kevzara® Kineret® Olumiant® Omvoh™ pen Orencia® subcutaneous Otezla®	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: - history and concurrent use of a corticosteroid • Nasal polyps: - history and concurrent use of an intranasal corticosteroid • Atopic dermatitis: - Trial with a topical prescription product for a duration of at least 3 months. - For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

Immunomodulators – Systemic

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic [CC, ST] (continued)		
	Rinvoq™ ER Siliq™ Simponi® Skyrizi® Skyrizi® On-Body Sotyktu™ Stelara® Taltz® Tezspire® pen Tremfya® Velsipity™ Xeljanz® Xeljanz® XR Yuflyma® Yusimry™	

Anti-inflammatories/Immunomodulators – Ophthalmic Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

New Clinical Information

- New Drug Entity: Miebo® (perfluorohexyloctane)
- Drug to be added to the therapeutic class: Eysuvis® (loteprednol)

Miebo® (perfluorohexyloctane)

Indications and Usage:

- MIEBO (perfluorohexyloctane ophthalmic solution) is a semifluorinated alkane indicated for treatment of the signs and symptoms of dry eye disease.

Dosage and Administration:

- Instill one drop of MIEBO four times daily into each eye.

Dosage Forms and Strengths:

- Ophthalmic solution: 100% perfluorohexyloctane

Contraindications:

- None

Miebo [package insert]. Bridgewater, NJ; Bausch & Lomb. May 2023.

Miebo® (perfluorohexyloctane)

Warnings and Precautions:

- Use with Contact Lenses: MIEBO should not be administered while wearing contact lenses. Advise patients that contact lenses should be removed prior to and for at least 30 minutes after administration.

Adverse Reactions:

- Most common ocular adverse reaction was blurred vision. Blurred vision was reported in less than 4% of individuals.

Clinical Comparative Studies (within class):

- None

Storage:

- Store MIEBO at 15ºC to 25ºC (59ºF to 77ºF). After opening, MIEBO can be used until the expiration date on the bottle.

Miebo [package insert]. Bridgewater, NJ; Bausch & Lomb. May 2023.

Anti-inflammatories/Immunomodulators – Ophthalmic

Drug	FDA Approved and Medicaid Covered Indications	Dosing	Availability	Mechanism of Action
cyclosporine emulsion (Restasis®, Restasis Multidose®)	Increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca	1 drop in each eye twice daily (12 hours apart)	0.05% ophthalmic emulsion in 0.4 mL single-use, preservative-free containers (trays of 30 or 60) Restasis Multidose: 5.5 mL of 0.05% ophthalmic emulsion in a 10 mL bottle (preservative-free) (brand only)	Calcineurin inhibitor immunosuppressant
lifitegrast (Xiidra®)	Treatment of signs and symptoms of dry eye disease in adults	1 drop in each eye twice daily (12 hours apart)	5% ophthalmic emulsion in 0.2 mL single-use, preservative-free containers (carton of 60 single-use containers stored in foil pouches of 5 containers/pouch)	Lymphocyte function associated antigen-1 (LFA-1) antagonist
cyclosporine solution (Cequa®)	Increase tear production in patients with keratoconjunctivitis sicca (dry eye)	1 drop in each eye twice daily (12 hours apart)	0.09% ophthalmic solution in 0.25 mL single-use, preservative-free container vials (cartons of 60 vials)	Calcineurin inhibitor immunosuppressant
varenicline nasal spray (Tyrvaya®)	Treatment of the signs and symptoms of dry eye disease in adults	1 spray in each nostril twice daily (approximately 12 hours apart)	Nasal solution: 0.03 mg (0.05 mL)/spray; supplied as a carton containing 2 bottles of nasal spray; each bottle delivers 15-day supply (60 sprays)	Cholinergic agonist
cyclosporine emulsion (Verkazia®)	Treatment of vernal keratoconjunctivitis (VKC) in adults and children ≥ 4 years of age	1 drop 4 times daily into each affected eye	0.1% ophthalmic emulsion in low density polyethylene single-dose vials. Each vial contains 0.3 mL, 5 vials are packaged in an aluminum pouch. 24 pouches are packaged in a box.	Calcineurin inhibitor immunosuppressant
Cyclosporine solution (Vevye®)	Treatment of the signs and symptoms of dry eye disease	1 drop in each eye twice daily (12 hours apart)	0.1% ophthalmic solution. Multiple-dose eye drop bottle. Non-aqueous, non-preserved.	Calcineurin inhibitor immunosuppressant
perfluorohexyloctane (Miebo®)	Treatment of the signs and symptoms of dry eye disease (DED)	1 drop four times daily into affected eye(s)	Ophthalmic solution: 100% perfluorohexyloctane	Semifluorinated alkane
loteprednol (Eysuvis®)	Short-term (up to 14 days) treatment of dry eye disease signs and symptoms	1 to 2 drops into each eye 4 times a day	0.25% sterile suspension in a 8.3 mL multi-dose bottle	Corticosteroid

1 Restasis [package insert]. Irvine, CA; Allergan; July 2017. 2 Restasis Multidose [package insert]. Irvine, CA; Allergan; October 2016. 3 Verkazia [package insert]. Emeryville, CA; Santen; June 2022. 4 Cequa [package insert]. Cranbury, NJ; Sun; July 2022. 5 Xiidra [package insert]. Lexington, MA; Shire; June 2020. 5 Eysuvis [package insert]. Fort Worth, TX; Alcon; November 2023 7 Tyrvaya [package insert]. Princeton, NJ; Oyster Point Pharma; February 2024. 6. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC. August 2023. 7. Miebo [package insert]. Bridgewater, NJ; Bausch & Lomb. May 2023.

Anti-inflammatories/Immunomodulators – Ophthalmic

Drug	Contraindications	Warnings and Precautions	Most Common Adverse Reactions
cyclosporine emulsion (Restasis®, Restasis Multidose®)	Hypersensitivity	To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.	The most common adverse reaction following the use was ocular burning (17%)
lifitegrast (Xiidra®)	Hypersensitivity	None	The most common adverse reactions (incidence 5%-25%) following the use were instillation-site irritation, dysgeusia, and decreased visual acuity.
cyclosporine solution (Cequa®)	None	To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces	The most common adverse reactions following the use were instillation site pain (22%) and conjunctival hyperemia (6%)
varenicline nasal spray (Tyrvaya®)	None	None	The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation.
cyclosporine emulsion (Verkazia®)	None	To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces	The most common adverse reactions following the use were eye pain (12%) and eye pruritus (8%)
Cyclosporine solution (Vevye®)	None	Care should be taken to not touch the eye or other surfaces with the bottle tip to avoid potential for eye injury and/or contamination	The most common adverse reaction following use were instillation site reactions (8%).
perfluorohexyloctane (Miebo®)	None	Contact lenses should be removed prior to and for at least 30 minutes after the administration.	The most common adverse effects reported with perfluorohexyloctane in clinical trials were blurred vision and conjunctival redness (1% to 3% for both).
loteprednol (Eysuvis®)	Most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.	Delayed healing and corneal perforation, intraocular pressure increase, cataracts, bacterial infections, viral infections, fungal infections.	The most common adverse drug reaction following the use for two weeks was instillation site pain (5%)

1 Restasis [package insert]. Irvine, CA; Allergan; July 2017. 2 Restasis Multidose [package insert]. Irvine, CA; Allergan; October 2016. 3 Verkazia [package insert]. Emeryville, CA; Santen; June 2022. 4 Cequa [package insert]. Cranbury, NJ; Sun; July 2022. 5 Xiidra [package insert]. Lexington, MA; Shire; June 2020. 5 Eysuvis [package insert]. Fort Worth, TX; Alcon; November 2023 7 Tyrvaya [package insert]. Princeton, NJ; Oyster Point Pharma; February 2024. 6. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC. August 2023. 7. Miebo [package insert]. Bridgewater, NJ; Bausch & Lomb. May 2023.

Anti-inflammatories/Immunomodulators – Ophthalmic

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
XII. Ophthalmics		
Anti-inflammatories/Immunomodulators – Ophthalmic CC		
Restasis® BLTG Restasis MultiDose® Xiidra®	Cequa® cyclosporine (gen Restasis®) Miebo™ Tyrvaya™ Verkazia® Vevye®	**CLINICAL CRITERIA (CC)** • Diagnosis documentation required to justify utilization as a first line agent or attempt treatment with an artificial tear, gel, or ointment.

Phosphate Binders/Regulators Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

New Clinical Information

- New Drug Entity: Xphozah® (tenapanor)
- Label Revisions: Fosrenol ® (lanthanum carbonate)

Xphozah® (tenapanor)

➢ Indications and Usage:

- XPHOZAH is a sodium hydrogen exchanger 3 (NHE3) inhibitor indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy

➢ Dosage and Administration:

- Recommended dosage: 30 mg orally twice daily before the morning and evening meals.
- Manage serum phosphorus levels and tolerability with dosage adjustments.
- Take just prior to the first and last meals of the day.
- Instruct patients not to take right before a hemodialysis session, and instead take right before the next meal following dialysis.

Xphozah [package insert]. Waltham, MA; Ardelyx,Inc.; October 2023

Xphozah® (tenapanor)

Dosage Forms and Strengths:

- Tablets: 10 mg, 20 mg, 30 mg

Contraindications:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

Warnings and Precautions:

- Patients may experience severe diarrhea

Adverse Reactions:

- Most common adverse reaction in the combined clinical trials was diarrhea, reported by 43-53% of patients

Xphozah [package insert]. Waltham, MA; Ardelyx,Inc.; October 2023

Xphozah® (tenapanor)

➢ Drug Interactions:

- OATP2B1 Substrates: Potential for reduced exposure of the concomitant drug (e.g., enalapril). Monitor for signs related to loss of efficacy and adjust the dosage of the concomitantly administered drug as needed.
- Sodium Polystyrene Sulfonate (SPS): Separate administration by at least three hours.

➢ Special Populations:

- Tenapanor is essentially non-absorbed systemically, with plasma concentrations below the limit of quantification (less than 0.5 ng/mL) following oral administration. Therefore, maternal use is not expected to result in fetal exposure to the drug.
- There are no data available on the presence of tenapanor in either human or animal milk, its effects on milk production or its effects on the breastfed infant.
- XPHOZAH is contraindicated in patients less than 6 years of age
- Clinical studies of XPHOZAH did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently than younger patients.

➢ Clinical Comparative Studies (within class):

- None

Xphozah [package insert]. Waltham, MA; Ardelyx,Inc.; October 2023

Label Revisions

- **Fosrenol ® (lanthanum carbonate)**
  - Warnings and Precautions: FOSRENOL has radio-opaque properties and, therefore, may give the appearance typical of an imaging agent during abdominal X-ray procedures.

Auryxia [package insert]. Cambridge, MA; Keryx Biopharmaceuticals,Inc.; January 2024
Fosrenol [package insert]. Lexington, MA; Takeda Pharmaceuticals,Inc.; December 2023

Phosphate Binders/Regulators

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
XIV. Renal and Genitourinary		
Phosphate Binders/Regulators		
calcium acetate Renvela® tablet, powder pack BLTG sevelamer HCl (gen Renagel)	Auryxia® Fosrenol® lanthanum carbonate Phoslyra® sevelamer carbonate powder, tablet (gen Renvela) Velphoro® Xphozah®	

Rosacea Agents – Topical Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
May 16th, 2024

Overview:

- Rosacea is a common, chronic inflammatory facial eruption of unknown cause characterized by erythema and telangiectasia, and sometimes by recurrent, progressive crops of acneiform papules and pustules, usually on the central part of the face.
- Topical antimicrobials (metronidazole, azelaic acid, ivermectin) are generally tried first for treatment of rosacea, sometimes in combination with oral antimicrobials.
  - First-line treatment for erythema due to rosacea consists of behavioral intervention: avoidance of triggers of flushing, proper use of sun protection, and gentle skin care.
  - Data from studies in patients with papulopustular rosacea suggests that agents primarily used for papulopustular disease (e.g., topical antimicrobials) may also have benefit for the reduction of rosacea-associated facial erythema.

UpToDate: Management of rosacea
Medical Letter. Drugs for Rosacea. 2016;58(1487):16-17

Azelaic acid (Finacea®)

Indications and Usage:

- Topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

Dosage and Administration:

- Apply to affected area(s) twice daily.

Dosage Forms and Strengths:

- 15% gel: Finacea, azelaic acid
- 15% foam: Finacea

Warnings and Precautions:

- Known hypersensitivity to any component of the gel.
- Skin irritation (i.e., pruritus, burning or stinging) may occur, usually during the first few weeks of treatment.
- There have been isolated reports of hypopigmentation after the use of azelaic acid.
- Reported to cause irritation of the eyes. Avoid contact with the eyes and mucous membranes.

Adverse Reactions:

- Burning/stinging/tingling (29%), pruritus (11%), scaling/dry skin/xerosis (8%) and erythema/irritation (4%).

Ivermectin

Indications and Usage:

- Treatment of inflammatory lesions of rosacea.

Dosage and Administration:

- Apply to the affected areas once daily.

Dosage Forms and Strengths:

- Cream: 1%

Warnings and Precautions:

- None

Adverse Reactions:

- Skin burning sensation and skin irritation (incidence ≤1%).

Metronidazole (Noritate, Rosadan® Kit)

Indications and Usage:

- Topical treatment of rosacea.

Dosage and Administration:

- 1%: Apply to the affected areas once daily.
- 0.75%: Apply to the affected areas twice daily.

Dosage Forms and Strengths:

- Cream, Gel: 0.75%, 1%, Lotion: 0.75%, Kit: 0.75% plus cleanser

Contraindications:

- Known hypersensitivity to parabens or any components of the formulation

Warnings and Precautions:

- Avoid contact in eyes

Adverse Reactions:

- Transient skin irritation, dryness and stinging, possible contact dermatitis.

Rosacea Agents – Topical

Drug	FDA Approved and Medicaid Covered Indications	Dosing Frequency	Dosage Forms	Mechanism of Action
Azelaic acid (Finacea®)	Topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.	Apply to affected area(s) twice daily.	Gel: 15% Foam: 15%	The exact mechanism of action is not known. Been shown to possess antimicrobial activity against Propionibacterium acnes and Staphylococcus epidermidis, possibly due to the inhibition of microbial cellular protein synthesis. A normalization of keratinization leading to an anticomedonal effect may also contribute to its clinical activity
Ivermectin	Treatment of inflammatory lesions of rosacea.	Apply to the affected areas once daily.	Cream: 1%	Unknown. Ivermectin is a semi-synthetic derivative isolated from the fermentation of Streptomyces avermitilis that belongs to the avermectin family of macrocyclic lactones.
Metronidazole (Noritate, Rosadan® Kit)	Rosacea	1%: Apply to the affected areas once daily. 0.75%: Apply to the affected areas twice daily.	Cream, Gel: 0.75%, 1% Lotion: 0.75% Kit: 0.75% plus cleanser	The exact mechanism of action of topical metronidazole for reducing inflammatory lesions of acne rosacea is unknown. It is possibly due to an antibacterial or an anti-inflammatory effect.

Rosacea Agents – Topical

Drug	Contraindications	Warnings and Precautions	Most Common Adverse Reactions
Azelaic acid (Finacea®)	None	▪ Known hypersensitivity to any component of the gel ▪ Skin irritation (i.e., pruritus, burning or stinging) may occur, usually during the first few weeks of treatment. ▪ There have been isolated reports of hypopigmentation after the use of azelaic acid. ▪ Reported to cause irritation of the eyes. Avoid contact with the eyes and mucous membranes.	Burning/stinging/tingling (29%), pruritus (11%), scaling/dry skin/xerosis (8%) and erythema/irritation (4%).
Ivermectin	None	None	Skin burning sensation and skin irritation (incidence ≤ 1%).
Metronidazole (Noritate, Rosadan® Kit)	Known hypersensitivity to parabens or any components of the formulation	▪ Avoid contact in eyes	Transient skin irritation, dryness and stinging, possible contact dermatitis.

Rosacea Agents – Topical

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Rosacea Agents • azelaic acid (Finacea®) * • brimonidine gel pump • ivermectin • oxymetazoline HCl (Rhofade®) • doxycycline IR/DR	• Trial with topical metronidazole product. *does not apply to azelaic acid (Finacea®)		• Confirmation of FDA-approved or compendia-supported indication *does not apply to azelaic acid (Finacea®)

New York State

Drug Utilization Review Board Meeting

May 16, 2024

Current NYRx Preferred Drug List for the 13 Drug Classes on the Agenda

NEW YORK STATE | Department of Health

Clinical Criteria for Non-Preferred Products

Non-Preferred Products remain available through the prior authorization process.

1. The preferred drug has been tried by the patient and has failed to produce the desired health outcome.

   Q: Has your patient experienced treatment failure with a preferred product?

2. The patient has tried the preferred drug and has experienced unacceptable adverse effects.

   Q: Has your patient experienced an adverse drug reaction with a preferred product?

3. The patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated

   Q: Is there a documented history of successful therapeutic control with a non-preferred product and transition to a preferred product is medically contraindicated?

4. Other clinical indications for use of a non-preferred drug, which shall include consideration of the medical needs of special populations.

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IV. Central Nervous System		
Movement Disorder Agents [CC]		
Austedo® Ingrezza® Ingrezza® titration pack tetrabenazine	Austedo® XR Xenazine®	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for an FDA-approved or compendia-supported indication

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IV. Central Nervous System		
Multiple Sclerosis Agents		
Avonex® Betaseron® Copaxone® 20 mg/mL BLTG dimethyl fumarate DR fingolimod (gen Gilenya®) 1 teriflunomide (gen Aubagio®) 1	Aubagio® Bafiertam™ Copaxone® 40 mg/mL Extavia® Gilenya® glatiramer Kesimpta® Mavenclad® Mayzent® Plegridy® Ponvory™ F/Q/D Rebif® Rebif® Rebidose® Tascenso ODT™ Tecfidera® Vumerity® Zeposia® CC, ST	**CLINICAL CRITERIA (CC)** • **Zeposia® (ozanimod):** Confirm diagnosis for FDA- or compendia-supported use **STEP THERAPY (ST)** • **Zeposia® (ozanimod):** For an indication of Ulcerative Colitis – Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD), and; – Trial of a preferred systemic immunomodulator **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • **Ponvory™ (ponesimod) starter pack**; maximum quantity is 14, no refills • **Ponvory™ (ponesimod)**; maintenance limited to a 30-day supply

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
V. Dermatologic Agents		
Anti-Fungals – Topical		
ciclopirox cream, suspension, shampoo clotrimazole OTC clotrimazole Rx clotrimazole/betamethasone cream ketoconazole cream ketoconazole 2% shampoo miconazole OTC nystatin cream, ointment, powder nystatin/triamcinolone terbinafine OTC tolnaftate OTC	Alevazol OTC butenafine (gen Mentax®) Ciclodan® cream ciclopirox gel clotrimazole/betamethasone lotion econazole Ertaczo® Extina® ketoconazole foam Loprox® shampoo luliconazole Luzu® Mentax® miconazole/zinc/petrolatum (gen Vusion®) F/Q/D naftifine Naftin® oxiconazole Oxistat® Vusion® F/Q/D	**FREQUENCY/QUANTITY/DURATION (F/Q/D)** • **Vusion® 50 gm ointment** –Maximum 100 grams in a 90-day time period

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Anti-Fungals, Topical – for Onychomycosis • ciclopirox 8% solution • efinaconazole (Jublia®) • tavaborole (Kerydin®)	• Trial with an oral antifungal agent* prior to use of ciclopirox 8% solution *terbinafine (Lamisil®) tablets; griseofulvin (Gris PEG®) oral suspension, ultramicronized tablets micronized tablets; itraconazole (Sporanox®,) tablets, oral solution • Trial with ciclopirox 8% solution prior to the use of other topical antifungals [efinaconazole (Jublia®) or tavaborole (Kerydin®)]		

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
V. Dermatologic Agents		
Immunomodulators – Topical [CC]		
pimecrolimus tacrolimus	Elidel® Protopic®	**CLINICAL CRITERIA** • All prescriptions require prior authorization • Refills on prescriptions are allowed

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Atopic Dermatitis Agents • crisaborole (Eucrisa®) • ruxolitinib (Opzelura™)	• Trial with a medium or high potency prescription topical steroid within the last 3 months	**QUANTITY LIMITS:** • 100 gm/30 days (crisaborole) • 240 gm/30 days (ruxolitinib)	• Confirm diagnosis of FDA-approved or compendia-supported Medicaid covered indication • ruxolitinib: age 12 years +

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Anabolic Steroids – Topical CDRP, F/Q/D		
testosterone gel testosterone pump	Androderm® AndroGel® pump Fortesta® Testim® Vogelxo	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • For diagnosis of hypogonadotropic or primary hypogonadism: – Requires documented low testosterone concentration with two tests prior to initiation of therapy. – Require documented testosterone therapeutic concentration to confirm response after initiation of therapy. • For diagnosis of delayed puberty: – Requires documentation that growth hormone deficiency has been ruled out prior to initiation of therapy. The Anabolic Steroid fax form can be found at: https://newyork.fhsc.com/downloads/providers/NYRx_CDRP_PA_Worksheet_Prescribers_Anabolic_Steroids.pdf For diagnosis of gender dysphoria, see Hormone Replacement Therapy for Treatment of Gender Dysphoria coverage in the DUR section of this document **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Limitations for anabolic steroid products based on approved FDA labeled daily dosing and documented diagnosis: – Duration limit of 6 months for delayed puberty

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Growth Hormones CC, CDRP		
Genotropin® Norditropin®	Humatrope® Ngenla™ Nutropin AQ® Omnitrope® Saizen® Skytrofa® Sogroya® Zomacton®	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • Prescribers or their authorized agents may call or submit a fax request for a PA for beneficiaries 18 years of age or older **CLINICAL CRITERIA (CC)** • Patient-specific considerations for drug selection include concerns related to use of a non-preferred agent for FDA-approved indications that are not listed for a preferred agent. • Confirm diagnosis of FDA-approved or compendia-supported indication

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VII. Gastrointestinal		
Proton Pump Inhibitors (PPIs) F/Q/D		
Dexilant® DO, BLTG esomeprazole magnesium Rx capsule lansoprazole Rx capsule omeprazole Rx pantoprazole tablet Protonix suspension BLTG rabeprazole Zegerid® Rx BLTG	Aciphex® dexlansoprazole (gen Dexilant) esomeprazole magnesium tablet OTC esomeprazole capsules OTC esomeprazole suspension Konvomep™ lansoprazole Rx ODT Nexium® RX DO omeprazole OTC omeprazole/sodium bicarbonate Rx omeprazole/sodium bicarbonate OTC pantoprazole suspension Prevacid® OTC Prevacid® Rx DO Prilosec® Rx Protonix® tablet	**DOSE OPTIMIZATION (DO)** • See Dose Optimization Chart for affected strengths **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Quantity limits: – Once daily dosing for: ○ GERD ○ erosive esophagitis ○ healing and maintenance of duodenal/gastric ulcers (including NSAID-induced) ○ prevention of NSAID-induced ulcers – Twice daily dosing for: ○ hypersecretory conditions ○ Barrett's esophagitis ○ H. pylori ○ refractory GERD • Duration limits: – 90 days for: ○ GERD – 365 days for: ○ Maintenance treatment of duodenal ulcers, or erosive esophagitis – 14 days for: ○ H. pylori

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VIII. Hematological Agents		
Hemophilia Agents – Factor VIII		
Advate® Adynovate® Afstyla® Eloctate® Esperoct® Hemofil® M Humate-P® Jivi® Koate® Kogenate® FS Kovaltry® Novoeight® Nuwiq® Obizur® Recombinate™ Xyntha® Xyntha® Solofuse	Altuviiio™	

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Abrilada™ (adalimumab-AFZB) Actemra® subcutaneous adalimumab-AACF (gen Idacio®) adalimumab-FKJP (gen Hulio®) adalimumab-ADAZ (gen Hyrimoz®) adalimumab-ADBM (gen Cyltezo®) Adbry™ Amjevita™ Bimzelx® Cibinqo™ Cimzia® Cyltezo® (adalimumab-ADMB) Entyvio pen® Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® Ilumya® Kevzara® Kineret® Olumiant® Omvoh™ pen Orencia® subcutaneous Otezla® Rinvoq™ ER	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: – history and concurrent use of a corticosteroid • Nasal polyps: – history and concurrent use of an intranasal corticosteroid • Atopic dermatitis: – Trial with a topical prescription product for a duration of at least 3 months. – For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST (continued)		
	Siliq™ Simponi® Skyrizi® Skyrizi® On-Body Sotyktu™ Stelara® Taltz® Tezspire® pen Tremfya® Velsipity™ Xeljanz® Xeljanz® XR Yuflyma® Yusimry™	

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
XII. Ophthalmics		
Anti-inflammatories/Immunomodulators – Ophthalmic CC		
Restasis® BLTG Restasis MultiDose® Xiidra®	Cequa® cyclosporine (gen Restasis®) Miebo™ Tyrvaya™ Verkazia® Vevye®	**CLINICAL CRITERIA (CC)** • Diagnosis documentation required to justify utilization as a first line agent or attempt treatment with an artificial tear, gel, or ointment.

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
XII. Ophthalmics		
Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) – Ophthalmic		
diclofenac flurbiprofen Ilevro® ketorolac ketorolac LS	Acular® Acular LS® Acuvail® bromfenac BromSite® Nevanac® Prolensa®	

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
XIV. Renal and Genitourinary		
Phosphate Binders/Regulators		
calcium acetate Renvela® tablet, powder pack BLTG sevelamer HCl (gen Renagel)	Auryxia™ Fosrenol® lanthanum carbonate Phoslyra® sevelamer carbonate powder, tablet (gen Renvela) Velphoro® Xphozah®	

New York State Medicaid Drug Utilization Review Board Meeting – May 16, 2024
Preferred Drug Program – Drug Class Review

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Rosacea Agents • azelaic acid (Finacea®) * • brimonidine gel pump • ivermectin • oxymetazoline HCl (Rhofade®) • doxycycline IR/DR	• Trial with topical metronidazole product. *does not apply to azelaic acid (Finacea®)		• Confirmation of FDA-approved or compendia-supported indication *does not apply to azelaic acid (Finacea®)

Medicaid NYRx Preferred Drug Program

New York State Medicaid Preferred Drug List (fhsc.com)

Drug Utilization Review (DUR) (ny.gov)

Information - Formulary File (emedny.org)

NEW YORK STATE | Department of Health