Opzelura (ruxolitinib) Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
06-16-2025

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Opzelura® (ruxolitinib) Cream	Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older Limitation of Use: • Use of Opzelura in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Atopic Dermatitis	Atopic dermatitis (AD), also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and 1-5% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children; flexure involvement in any age group, with sparing of groin and axillary regions.(2) Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks.(3) Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with topical emollient/moisturizer use and conventional topical therapies (including corticosteroids and calcineurin inhibitors).(3,5) Moisturizers reduce signs,

	symptoms, and inflammation in AD, and can improve severity while also increasing time between flares. Moisturizers are considered generally safe and are strongly recommended to be used as part of a treatment regimen for AD, either as monotherapy or as concurrent use with pharmacologic treatments.(4) Topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile. They can be utilized individually or in combination with other topical, physical, and/or systemic treatments; as different classes of treatment have different mechanisms of action, combining therapies allows for the targeting of AD via multiple disease pathways. The American Academy of Dermatology (AAD) strongly recommends the following topical agents:(4) • Topical corticosteroids (TCS) • Calcineurin inhibitors (TCIs) (e.g., tacrolimus, pimecrolimus) • Topical PDE-4 inhibitors (e.g., crisaborole) [mild to moderate AD] • Topical JAK inhibitors (e.g., ruxolitinib) [mild to moderate AD] TCS are the most commonly utilized FDA-approved therapies in AD and are commonly used as first-line treatment for mild-to severe dermatitis in all skin regions. TCS target a variety of immune cells and suppress the release of proinflammatory cytokines. High to very high (super) potency TCS can be used to control flares and treat severe disease, while medium potency TCS are utilized for longer courses and as maintenance therapy. Lower potency TCS may be used, and it is important to consider the anatomical site (i.e., using lower potency agents on the face, neck, genitals, and body folds) and severity of the disease when choosing a steroid potency. Most studies of TCS in AD management involve twice daily application, but some studies (particularly for potent TCS) suggest once daily use may be sufficient. Traditionally, TCS were stopped once AD signs and symptoms of an AD flare were controlled. Maintenance in between AD flares with once to twice weekly use of TCS is another approach.(4) TCIs are a safe anti-inflammatory option for mild-to-severe AD, particularly when there is concern for adverse events secondary to corticosteroid use. Both tacrolimus and pimecrolimus have been shown to be effective in treating AD, but pimecrolimus may be more appropriate for patients who have milder disease or are sensitive to local reactions.(4) Prescribing information for pimecrolimus cream and tacrolimus ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.(7,8)
Vitiligo	Vitiligo is an acquired skin pigmentation disorder characterized by well defined, depigmented areas of the skin. The depigmentation is due to a loss of epidermal melanocytes. Vitiligo can present in a localized or generalized distribution, with the lesions coalescing into larger depigmented areas. The underlying cause of vitiligo is yet unknown.(10) Vitiligo is commonly classified into two different forms, segmental and non-segmental. Non-segmental vitiligo (NSV) tends to evolve over time in both distribution and extension patterns. NSV is an umbrella term for a number of different subtypes of vitiligo. These include acrofacial, generalized, mucosal (multifocal), and universal. NSV is characterized by depigmented lesions that vary in size and often involve both sides of the body. Involvement of the scalp and other hair-bearing areas may manifest with patches of gray or white hairs, while body hair is generally spared. Segmental vitiligo (SV) tends to have an earlier age of onset, that rapidly progresses but has a limited course. Depigmentation spreads within a segment within 6-24 months and then stops. Hair follicles are more frequently involved early in the disease course with SV, with up to 50% of patients exhibiting poliosis, a localized cluster of white hair shafts, in affected areas.(11) The diagnosis of vitiligo is based off of clinical presentation and with a Woods lamp, which is a handheld ultraviolet device. The Woods lamp is also used to track progression of lesions over time. There are a number of other indications that can mimic vitiligo and it is important to rule those out with a close examination of the skin. Vitiligo does not cause scaling or textural changes in the skin.(10)

	Topical corticosteroids (TCS) are recommended as first line treatment for vitiligo.(6,12) TCS have been found to be effective in areas of the face and neck, extrafacial locations, and limited treatment areas.(6,14) A (medium) potent to very potent TCS should be used for treatment.(12,14) Mometasone furoate, a medium potency TCS, is often recommended due to a decreased risk of side effects.(6,9) The risk of local side effects, including skin atrophy, should be evaluated when determining an appropriate treatment regimen.(6,14) When using TCS on the face, the periocular area should be avoided.(12) TCS should also be used with caution in areas of thinner skin, such as the axillar region and genital area. Although once daily dosing is used for the treatment of vitiligo, using an intermittent dosing regimen can reduce the risk of side effects. Intermittent dosing regimens of 1 week on and at least 1 week off, or 2 weeks on and 2 weeks off, have been suggested.(12,14) Topical calcineurin inhibitors (TCIs) can be considered as an alternative treatment to TCS for areas of the face, neck, groin, and axillary.(14) TCIs have been noted to be less effective or not effective at all for extrafacial regions.(6,14) The topical safety profile of TCIs is advantageous compared to TCS, especially the risk of skin atrophy.(9,14) This allows them to be used long term and in areas where the use of potent TCS may not be appropriate.(6,14) The minimal treatment period for evaluation of efficacy has not been established, but the treatment duration in studies ranged from 10 weeks to 18 months.(9) Topical therapies should be evaluated every 3 to 6 months to check for improvement.(12) Both TCS and TCIs can be considered for maintenance treatment in vitiligo after successful repigmentation, although a less frequent dosing regimen should be used. Ruxolitinib, a topical JAK-inhibitor, is the first FDA approved drug for non-segmental vitiligo. At this time, there is no sufficient data to support the use of topical ruxolitinib as a maintenance therapy.(13)
Efficacy	*Atopic Dermatitis*(1) Two double-blind, randomized, vehicle-controlled trials of identical design (TRuE-AD1 and TRuE-AD2, NCT03745638 and NCT03745651, respectively) enrolled a total of 1249 adult and pediatric subjects aged 12 and older. Subjects had affected body surface area (BSA) of 3 to 20%, and an Investigator's Global Assessment (IGA) score of 2 (mild) to 3 (moderate) on a severity scale of 0 to 4. The baseline Itch Numerical Rating Scale (Itch NRS), defined as the 7-day average of the worst level of itch intensity in the last 24 hours, was 5 on a scale of 0 to 10. In both trials, subjects were randomized 2:2:1 to treatment with Opzelura, ruxolitinib cream, 0.75%, or vehicle cream twice daily (BID) for 8 weeks. The primary efficacy endpoint was the proportion of subjects at week 8 achieving IGA treatment success (IGA-TS) defined as a score of 0 (clear) or 1 (almost clear) with greater than or equal to 2 grade improvement from baseline. Efficacy was also assessed using a greater than or equal to 4-point improvement in Itch NRS. Opzelura was 38.9% and 44.1% more effective than placebo for IGA-TS, and 36.7% and 35.8% more effective than placebo for Itch NRS in TRuE-AD1 and TRuE-AD2 respectively. Patients should stop using Opzelura when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be re-examined by their healthcare provider. *Nonsegmental Vitiligo*(1) Two double-blind, randomized, vehicle-controlled trials of identical design (TRuE-V1 and TRuE-V2, NCT04052425 and NCT04057573, respectively) enrolled a total of 674 adult and pediatric subjects aged 12 years and older. Subjects had depigmented areas affecting greater than or equal to 0.5% facial body surface area (F-BSA), greater than or equal to 3% non-facial BSA, and total body vitiligo area (facial and non-facial, including hands, feet, upper and lower extremities, and trunk body areas) of up to 10% BSA.

	In both trials, subjects were randomized 2:1 to treatment with Opzelura or vehicle cream twice daily (BID) for 24 weeks followed by an additional 28 weeks of treatment with Opzelura twice daily for all subjects. Lesions on the face were assessed with the facial Vitiligo Area Scoring Index (F-VASI) and lesions on the total body (including the face) were assessed with the total body Vitiligo Area Scoring Index (T-VASI). The primary efficacy endpoint was the proportion of subjects achieving at least 75% improvement in F-VASI (F-VASI75) at week 24, and the proportion of participants achieving at least 90% improvement in F-VASI (F-VASI90) was also evaluated. Opzelura was 22.5% and 16.9% more effective than placebo for F-VASI75, and 13.3% and 13.5% more effective than placebo for F-VASI90 in TRuE-V1 and TRuE-V2 respectively. Satisfactory patient response may require treatment with Opzelura for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.

Safety	Opzelura carries the following boxed warnings:(1)
	
	• Serious infections leading to hospitalization or death have occurred in patients receiving oral Janus kinase (JAK) inhibitors for inflammatory conditions
	  ○ Reported infections include:
	  ▪ Active tuberculosis, which may present with pulmonary or extrapulmonary disease
	  ▪ Invasive fungal infections, including cryptococcosis and pneumocystosis
	  ▪ Bacterial, viral, and other infections due to opportunistic pathogens
	  ○ Avoid use of Opzelura in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt Opzelura until the infection is controlled. The risks and benefits of treatment with Opzelura should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Opzelura.
	• A higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor compared with a TNF blocker for RA.
	• Malignancies, including non-melanoma skin cancer (NMSC), were reported in patients treated with Opzelura. Lymphoma and other malignancies (excluding NMSC) have occurred at a higher rate in patients receiving oral JAK inhibitors used to treat inflammatory conditions compared to TNF blockers. Patients who are current or past smokers are at additional increased risk.
	• In patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed in patients treated with an oral JAK inhibitor compared with a TNF blocker for RA. Patients who are current or past smokers are at additional increased risk. Discontinue Opzelura in patients that have experienced a myocardial infarction or stroke.
	• Thromboembolic events were observed in clinical trials with Opzelura. Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors for inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of thrombosis was observed in patients treated with an oral JAK inhibitor compared with a TNF blocker for RA. Avoid Opzelura in patients at increased risk of thrombosis. If symptoms of thrombosis occur, discontinue Opzelura and treat appropriately.
	
	Opzelura has no FDA labeled contraindications for use.(1)

	Opzelura for the treatment of atopic dermatitis may be applied to affected areas of up to 20% body surface area. Opzelura for the treatment of nonsegmental vitiligo may be applied to affected areas of up to 10% body surface area.(1) Do not use more than one 60 gram tube per week or one 100 gram tube per 2 weeks.(1)

REFERENCES

Number	Reference
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3	Sidbury R, Tom WL, Bergman JN, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol. 2014 Dec;71(6):1218-33.
4	Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
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7	Pimecrolimus cream prescribing information. Oceanside Pharmaceuticals. September 2020.
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9	Taieb A, Alomar A, Böhm M, et al. Guidelines for the management of vitiligo: the European Dermatology Forum consensus. *British Journal of Dermatology*. 2012;168(1):5-19. doi:10.1111/j.1365-2133.2012.11197.x
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13	Van Geel N, Speeckaert R, Taïeb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task Force Part 1: towards a new management algorithm. *Journal of the European Academy of Dermatology and Venereology*. 2023;37(11):2173-2184. doi:10.1111/jdv.19451
14	Seneschal J, Speeckaert R, Taïeb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the international Vitiligo Task Force-Part 2: Specific treatment recommendations. *Journal of the European Academy of Dermatology and Venereology*. 2023;37(11):2185-2195. doi:10.1111/jdv.19450

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Opzelura	ruxolitinib phosphate cream	1.5 %	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	60	Grams	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Opzelura	ruxolitinib phosphate cream	1.5 %	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of mild to moderate atopic dermatitis (AD) AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. The patient is NOT immunocompromised **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to at least a low-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to at least a low-potency topical corticosteroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids used in the treatment of AD **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor used in the treatment of AD after at least a 6-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **AND** 5. BOTH of the following:

Module	Clinical Criteria for Approval
	A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** B. The patient has a diagnosis of nonsegmental vitiligo AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 10% **AND** 2. ONE of the following: A. The patient has vitiligo impacting areas OTHER THAN the face, neck, axillary, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo after at least a 2-week duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo **OR** 3. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of nonsegmental vitiligo **OR** B. The patient has vitiligo on the face, neck, axillary, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo after at least a 2-week duration of therapy **OR** 2. The patient has tried and had an inadequate response to a topical calcineurin inhibitor used in the treatment of nonsegmental vitiligo **OR** 3. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid OR a topical calcineurin inhibitor used in the treatment of nonsegmental vitiligo **OR** 4. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids AND ALL topical calcineurin inhibitors used in the treatment of nonsegmental vitiligo **OR** C. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Avtozma (tocilizumab-anoh) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb) Infliximab

Contraindicated as Concomitant Therapy
Kevzara (sarilumab)
Kineret (anakinra)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omlyclo (omalizumab-igec)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Otulfi (ustekinumab-aauz)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
Stelara (ustekinumab)
Steqeyma (ustekinumab-stba)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Ustekinumab
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yesintek (ustekinumab-kfce)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)