COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 12/12/2022 Notification Posted: 10/28/2022

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Revisions are effective the first of the month following a 45-day notification and comment period.

NEW UM PROGRAM			
Mounjaro (tirzepatide injection)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Mounjaro (tirzepatide injection)

Generic name: tirzepatide injection
Brand name: Mounjaro
Medispan GPI: 2717308000D2** MON
Medication class: Glucagonlike Peptide (GLP) 1 Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP) receptor Agonist
FDA-approved uses: **Type 2 diabetes mellitus (T2DM)**

Usual dose range:
T2DM Initial: 2.5mg weekly for 4 weeks Maintenance: 5-15mg weekly

Duration of Authorization:
Initial: 4 months
Ongoing: 4 months – not meeting goals (A1c >7%)
12 months – meeting goals (A1c <7%)

Estimated Cost: $15199.60 per patient per year (AWP)

Criteria for use for T2DM

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient must be diagnosed with uncontrolled type 2 diabetes mellitus (defined as an A1c of 7.0% or higher)
- Patient has failure, contraindication, or intolerance to maximum therapeutic dose metformin immediate or extended release (target 2000mg total daily dose) prior to authorization. Failure is defined as not meeting ADA treatment goals (A1c > 7%) despite adequate compliance (>80% MPR) for at least the 3 months immediately prior to the request.
    - Trial and failure of a second generic antidiabetic (sulfonylureas, pioglitazone, repaglinide) is encouraged, but not required for authorization.
    - Provider may apply a statement confirming access outside of the benefit

  -AND-
- Patient has failure (as defined as not meeting ADA treatment goals (A1c > 7%) despite adequate compliance (>80% MPR) for at least the 3 months immediately prior to the request), contraindication, or intolerance to at least one of the following:
    - Bydureon
    - Byetta
    - Ozempic
    - Rybelsus
    - Trulicity
    - Victoza
- May be used as an adjunctive agent or alternative monotherapy for patients who fail initial therapy with lifestyle intervention and metformin or who cannot take metformin. May be preferred when weight loss is desired and/or in patients with an HbA1c relatively far from goal (eg, HbA1c 9% to 10%) and type 1 diabetes is not likely; use has not been associated with improved or worsened cardiovascular outcomes.
- Due to lack of additive glycemic benefit, use in combination with a dipeptidyl peptidase-4 inhibitor should be avoided.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
    - **Of note, as of 8-17-22 – for the indication of T2DM renewals will not require formal chart notes. MedOne will accept updated A1c from last renewal as clinical documentation of efficacy of treatment for patients meeting goal or clinically stable on treatment.**
- Patient demonstrates adequate compliance as defined as an MPR >80%.
    - Provider may apply a statement confirming access outside of the benefit or addressing correction in compliance for a 4-month authorization to reassess patients MPR

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- History of or family history of medullary thyroid carcinoma.
- Patients with multiple endocrine neoplasia syndrome type 2.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18 - safety and effectiveness in pediatric patients have not been established.

- Patients with Diabetes Mellitus Type 1.
- If indication is limited to morbid obesity or other metabolic syndrome outside of Diabetes Mellitus Type 2.

Special Considerations:

- Evaluate, correct, and maintain postsurgical fluid requirements and volume status prior to initiating therapy, and closely monitor the patient for the duration of therapy; acute and chronic kidney failure exacerbation may occur. A majority of cases occurred in patients with nausea, vomiting, diarrhea, and/or dehydration. Nausea is common and fluid intake may be more difficult after gastric bypass, sleeve gastrectomy, and gastric band.
- Closely monitor for efficacy and assess for signs and symptoms of pancreatitis if therapy is initiated after surgery; gastric bypass and sleeve gastrectomy (but not gastric band) significantly increase endogenous postprandial GLP-1 concentrations. Administration of exogenous GLP-1 receptor agonists may be redundant to surgery effects.
- Tirzepatide slows gastric emptying, which may alter the absorption of other medications. Monitor narrow therapeutic index medications for increased or decreased response.
- Do not use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis; not a substitute for insulin.

References:

1. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2022.
2. Mechanick JI, Youdim A, Jones DB, et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient--2013 update: cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery. Surg Obes Relat Dis. 2013;9(2):159-191.[PubMed 23537696]10.1016/j.soard.2012.12.010
3. Korner J, Inabnet W, Febres G, et al. Prospective study of gut hormone and metabolic changes after adjustable gastric banding and Roux-en-Y gastric bypass. Int J Obes (Lond). 2009;33(7):786-795.[PubMed 19417773]10.1038/ijo.2009.79
4. Peterli R, Steinert RE, Woelnerhanssen B, et al. Metabolic and hormonal changes after laparoscopic Roux-en-Y gastric bypass and sleeve gastrectomy: a randomized, prospective trial. Obes Surg. 2012;22(5):740-748

MedOne Clinical Review Subcommittee Approval: Date: 10-26-22

Initial adoption: 10-26-22
Revised: 10-26-22
10-26-22 Pricing based on AWP as of 9-22-22

Effective Date (most recent revisions): 12-12-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

NEW UM PROGRAM CRITERIA			
Orencia (abatacept)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Orencia (abatacept)

Generic name: abatacept
Brand name: Orencia
Medispan GPI: GPI 6640001000**** MONY
Medication class: Biologic – selective T-cell costimulation blocker
FDA-approved uses: **Graft-vs Host disease, acute, prophylaxis -Adult and pediatric**
Juvenile idiopathic arthritis (JIA)
Psoriatic arthritis

Rheumatoid arthritis

Usual dose range:

GVH disease- Adult	IV: 10 mg/kg (maximum 1000 mg/dose) on day -1, and days 5, 14, 28 post-transplant	
GVH disease - pediatric	Age 2 to <6 years: IV 15mg/kg on day -1 then 12mg/kg on days 5, 14, and 28 post transplant Age ≥6 years: 10mg/kg on day -1 and days 5, 14, and 28 post-transplant	
JIA		
10 to <25 kg	50 mg once weekly	
≥25 to <50 kg	87.5 mg once weekly	
≥50 kg	125 mg once weekly	
Psoriatic arthritis	125 mg once weekly	IV: weeks 0, 2, 4 and every 4 weeks <60 kg: 500 mg 60-100 kg: 750 mg >100 kg: 1000 mg
Rheumatoid arthritis	125 mg once weekly	IV: weeks 0, 2, 4, and every 4 weeks <60 kg: 500 mg 60-100 kg: 750 mg >100 kg: 1000 mg

Duration of Authorization:

Initial:	4 months
Ongoing:	12 months (except GVH disease 6 months)

Estimated Cost: $79,072.76 annually for SQ dosing.

Criteria for use for GVH disease (orphan drug designation and breakthrough approval)

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 2 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
    - Initial dose should be complete through medical benefits
        - This is a facility administered medication that must be reviewed and provided via the medical benefit. MedOne is the third-party-administrator of the prescription drug benefit only. Please resubmit the request through the medical carrier.
    - Patients who received pretransplant dose, may be approved for follow up doses through grandfather status up to three doses or day 28 post-transplant, whichever is sooner.
- Patient is undergoing hematopoietic stem cell transplantation from a matched or 1 allele mismatched unrelated donor
- Must be prescribed by, or in consultation with a Board Certified Oncologist
- Documentation of required baseline screening for viral infections (TB, HepB, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
- Orencia must be used in combination with immunosuppressant therapy (methotrexate and calcineurin inhibitor)
- Prophylaxis for Epstein-Barr virus should be initiated prior to Orencia.

Criteria for use for JIA

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Must be 2 years of age or older.
- Patient is clinically diagnosed with JIA
- Must be prescribed by, or in consultation with a Board Certified rheumatologist
- Documentation of required baseline screening for viral infections (TB, HepB, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
- Patient has failure, contraindication, or intolerance to at least ONE conventional systemic DMARD (azathioprine, hydroxychloroquine, leflunomide, methotrexate)

-AND-

- Patient has failure, contraindication, or intolerance to at least TWO preferred biologics (Enbrel, Humira, Xeljanz)

Criteria for use for Psoriatic Arthritis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Must be 18 years of age or older.
- Patient is clinically diagnosed with active Psoriatic Arthritis
- Must be prescribed by, or in consultation with a Rheumatologist or Dermatologist.
- Documentation of required baseline screening for viral infections (TB, HepB, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
- Patient has failure, contraindication, or intolerance to at least one conventional systemic DMARD (acitretin, cyclosporine, leflunomide, methotrexate, sulfasalazine).

-AND-

- Patient has failure, contraindication, or intolerance to at least TWO preferred biologics (Cosentyx, Enbrel, Humira, Stelara, Xeljanz)

Criteria for use for Indication Rheumatoid Arthritis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Must be 18 years of age or older.
- Patient is clinically diagnosed with active Rheumatoid Arthritis
- Must be prescribed by, or in consultation with a Rheumatologist
- Documentation of required baseline screening for viral infections (TB, HepB, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
- Patient has failure, contraindication, or intolerance to at least one conventional systemic DMARD (acitretin, cyclosporine, leflunomide, methotrexate, sulfasalazine).

-AND-

- Patient has failure, contraindication, or intolerance to at least TWO preferred biologics (Enbrel, Humira, Rinvoq, Xeljanz)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.

- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient has a positive screening for viral infection and is not currently receiving appropriate management.
- Patient is currently using another specialty treatment for their condition.

Special Considerations:

- May increase risk for infection. Serious and fatal infections reported especially in patients receiving concomitant immunosuppressive therapy. Monitor for signs and symptoms of infections. Caution should be exercised when considering the use in any patient with a history of new/recurrent infections, with conditions that predispose them to infections, or with chronic, latent, or localized infections. Patients who develop a new infection while undergoing treatment should be monitored closely. If a patient develops a serious infection, therapy should be discontinued.
- May increase risk for malignancy. Impact on the development and course of malignancy is not fully defined. Increase risk of lymphoma and lung cancer noted in trials but also associated with patients with RA. Skin cancers have also been observed. Periodic skin examinations are recommended.
- Use in caution with patients 65 years of age and older due to higher incidences of infection and malignancy.
- Do not give live immunizations while on abatacept or within 3 months of discontinuation. All immunizations should be completed prior to initiating therapy.

References:

5. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol Myers Squibb; 2021.
6. Lexi Comp- abatacept. 8/30/22. https://online.lexi.com/Orencia
7. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939. doi:10.1002/acr.24596[PubMed 34101387]

MedOne P&T Committee approval: Date: 9-7-22

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10-26-22 1. Pricing updated based off of AWP
Effective Date (most recent revisions): 12-12-2022

**Revisions are effective the first of the month following a 45 day notification and comment period.*

NEW UM PROGRAM CRITERIA			
Ryaltris (olopatadine HCl and mometasone nasal spray)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Ryaltris

(olopatadine HCl and mometasone nasal spray)

Generic name: olopatadine hydrochloride and mometasone furoate monohydrate nasal spray
Brand name: Ryaltris
Medispan GPI: 42995502601820 MON*
Medication class: Combination antihistamine/corticosteroid
FDA-approved uses: **Seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older**

Usual dose range:
Allergic Rhinitis 2 sprays in each nostril twice daily

Duration of Authorization:
Initial: ongoing

Estimated Cost: $298.80 per bottle

Criteria for use for seasonal allergic rhinitis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 12 years of age or older.
- Grandfather criteria allowed
  - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with seasonal allergic rhinitis
- Patient has failure, contraindication, or intolerance to at least TWO generic intranasal corticosteroids:
  - budesonide (generic Rhinocort)
  - fluticasone (generic Flonase)
  - mometasone (generic Nasonex)
  - triamcinolone acetonide (generic Nasacort)

  -AND-
- Patient has failure, contraindication, or intolerance to generic olopatadine

Criteria continuation of therapy

- n/a

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Documentation of allergenic cross-reactivity for corticosteroids is limited; however, the possibility of cross-sensitivity cannot be ruled out with certainty because of similarities in chemical structure and/or pharmacologic actions.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 12

Special Considerations:

- When recommended doses are exceeded, or in extremely sensitive individuals, mometasone may cause hypercortisolism or suppression of the hypothalamic-pituitary-adrenal axis. Reports of hypercortisolism are rare with topical corticosteroids. Withdrawal and discontinuation of a corticosteroids should be done slowly and carefully. Fatalities have occurred due to adrenal insufficiency in asthmatic patients during and after transfer from systemic corticosteroids to aerosol steroids; aerosol steroids do not provide the systemic steroid exposure needed to treat patients having trauma, surgery, or infections.
- Olopatadine may cause drowsiness in some patients; instruct patients to use caution when driving or operating machinery. Effects may be additive with ethanol ingestion and/or other CNS depressants.
- Avoid nasal corticosteroids (eg, mometasone) in patients with nasal septal ulcers, recent nasal surgery, or trauma until healing has occurred.
- Hypersensitivity reactions, including rash, pruritus, angioedema, and wheezing, have been reported.
- Prolonged use of corticosteroids (eg, mometasone) may increase the incidence of secondary infections, mask acute infections (including fungal infections), prolong or exacerbate viral infections, or limit the response to vaccines. Avoid exposure to chicken pox and/or measles if not immunized.
- May cause epistaxis, nasal ulceration, or septal perforation.

References:

8. Ryaltris (olopatadine/mometasone) [prescribing information]. Columbus, OH: Hikma Specialty USA Inc; July 2022.

MedOne P&T Committee approval: Date: 10-26-22

Initial adoption: 10-26-22
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10-26-22 2. Pricing updated based off of AWP (8-30-22)
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NEW UM PROGRAM CRITERIA			
Skytrofa (lonapegsomatropin-tcgd)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Skytrofa (lonapegsomatropin-tcgd)

Generic name: lonapegsomatropin-tcgd
Brand name: Skytrofa
Medispan GPI: 3010000380**** MONY
Medication class: Growth Hormone
FDA-approved uses: **Growth hormone deficiency**

Usual dose range:

Growth hormone deficiency	0.24 mg/kg given once-weekly in patients age 1 year and older who weigh at least 11.5kg

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: Weight based dosing - $13949.04 for 4 cartridges of 13.3mg

Criteria for use for Growth Hormone Deficiency

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Patient is clinically diagnosed with pediatric growth hormone deficiency as defined as ONE of the following
    - Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is >2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height
    - Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height
    - Growth velocity is > 2 SD below mean for age and gender
    - Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)
- Must be 1 year to 18 years of age, weighting at least 11.5kg
- Must be prescribed by, or in consultation with an endocrinologist
- Patient must also have one of the following:
    - For male patients:
        - Tanner stage less than IV
        - Bone age < 16 years measured in the past 12 months
    - For female patients:
        - Tanner stage less than IV
        - Bone age < 14 years measured in the past 12 months
- Documentation of the following is included:
    - TWO of the following provocative GH stimulation tests:
        - Arginine
        - Clonidine
        - Glucagon
        - Insulin
        - Levodopa
        - Growth hormone releasing hormone
    - Both GH response values are < 10 mcg/L
- Patient has failure, contraindication, or intolerance to Norditropin

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.
- Documentation of open epiphyses, a growth velocity of >2cm/yr, and patient has not reached expected height at time of visit.
- Ongoing duration of authorization may be reduced in patients nearing end of treatment course.

Contraindications:

- Hypersensitivity to lonapegsomatropin, somatropin, or any component of the formulation
- Acute critical illness after open heart surgery, abdominal surgery, or multiple accidental trauma
- Acute respiratory failure
- Closed epiphyses
- Active malignancy
- Active proliferative or severe nonproliferative diabetic retinopathy
- Prader-Willi syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient is 18 years or older, medication is not indicated for use in adults.

Special Considerations:

- Dosing:

Lonapegsomatropin Dosage in Children and Adolescents Weighing ≥11.5 kg	
Weight	Dose
11.5 to <14 kg	3 mg SUBQ once weekly
14 to <16.5 kg	3.6 mg SUBQ once weekly
16.5 to <20 kg	4.3 mg SUBQ once weekly
20 to <24 kg	5.2 mg SUBQ once weekly
24 to <29 kg	6.3 mg SUBQ once weekly
29 to <35 kg	7.6 mg SUBQ once weekly
35 to <42 kg	9.1 mg SUBQ once weekly
42 to <51 kg	11 mg SUBQ once weekly
51 to <60.5 kg	13.3 mg SUBQ once weekly
60.5 to <70 kg	15.2 mg SUBQ once weekly (using 2 cartridges of 7.6 mg each)
70 to <85 kg	18.2 mg SUBQ once weekly (using 2 cartridges of 9.1 mg each)
85 to 100 kg	22 mg SUBQ once weekly (using 2 cartridges of 11 mg each)

- For conversion from daily somatropin therapy, allow 8 hours between final somatropin dose and first dose of lonapegsomatropin.
- Has been rarely reported in pediatric patients receiving somatropin; incidence in children may be greater than adults. Consider pancreatitis diagnosis if abdominal pain occurs.
- Initiation of lonapegsomatropin is contraindicated with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure; mortality may be increased. Discontinuation of therapy may be necessary in patients with an acute critical illness.

- Patients who have or are at risk for pituitary hormone deficiency(ies) may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism with somatropin therapy; patients with previously diagnosed hypoadrenalism may require increased dosages of glucocorticoids due to the effects of somatropin. Excessive glucocorticoid therapy may inhibit the growth-promoting effects of somatropin in children.
- Patients who have or are at risk for pituitary hormone deficiency(ies) may be at risk for unmasking of central hypothyroidism with somatropin therapy. Untreated/undiagnosed hypothyroidism may decrease response to therapy, particularly the growth response in children.
- Sudden death has been reported in pediatric patients with Prader-Willi syndrome following the use of somatropin. The reported fatalities occurred in patients with ≥1 risk factor, including severe obesity, history of upper airway obstruction or sleep apnea, respiratory impairment, or unidentified respiratory infection; male patients may be at greater risk. Use of lonapegsomatropin is not indicated for the treatment of pediatric patients who have growth failure due to Prader-Willi syndrome.
- Progression of scoliosis may occur in children experiencing rapid growth.

References:

1. Skytrofa (lonapegsomatropin) [prescribing information]. Princeton, NJ: Ascendis Pharma Endocrinology Inc; August 2022.
2. 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2019;67(4):674-694. doi:10.1111/jgs.15767[PubMed 30693946]

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UM PROGRAM CRITERIA REVISED			
Tremfya (guselkumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Tremfya	1. Grandfathering criteria requirements explained 2. Pricing updated based off of AWP 3. Noted special considerations 4. Added scalp to sensitive areas for plaque psoriasis		

Prior Authorization Approval Criteria

Tremfya (guselkumab)

Generic name: Guselkumab
Brand name: Tremfya
Medispan GPI: GPI 9025054200**** MONY
Medication class: Interleukin Receptor Antagonist, IL-23i, Antipsoriatic, Monoclonal Antibody
FDA-approved uses: **Plaque psoriasis**
Psoriatic arthritis

Usual dose range:
Plaque psoriasis Initial: 100mg SQ at weeks 0 and 4 Maintenance: 100mg SQ every 8 weeks

Psoriatic arthritis	Initial: 100mg SQ at weeks 0 and 4	Maintenance: 100mg SQ every 8 weeks

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost:

$15,099.65/dose, $98,147.73 PPPY maintenance, $120,797.20 first year

Criteria for use for Plaque psoriasis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with moderate to severe plaque psoriasis
- Must be 18 years of age or older.
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Minimum 10% BSA involvement OR involvement of sensitive areas (hands, feet, face, scalp, genitals)
- Patient must have failure, intolerance, or contraindication to at least one conventional systemic DMARD (acitretin, cyclosporine, methotrexate, sulfasalazine)
  -AND-
- At least TWO category B medications (Humira, Enbrel, Cosenytx, Stelara, Skyrizi).

Criteria for use for Psoriatic arthritis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
- Please see policy and procedure "14 – Grandfather Status Authorization" for additional information.
- Patient is clinically diagnosed with psoriatic arthritis
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Must be 18 years of age or older.
- Must be prescribed by, or in consultation with a Rheumatologist or Dermatologist.
- Patient has documented failure after 3 months, contraindication, or intolerance to one oral generic (azathioprine, hydroxychloroquine, leflunomide, methotrexate) AND two preferred biologics (Enbrel, Humira, Cosentyx, Skyrizi, Stelara).

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.
- Patient demonstrates adequate compliance as defined as an MPR >80%. First dose is a 28 day supply, following doses are a 56 day supply.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient must not have active tuberculosis infection. Confirm by TB skin test, IGRA, or chest X-ray.

Special Considerations:

- Antibody formation: Formation of neutralizing anti-drug antibodies may occur but has not been associated with loss of efficacy for guselkumab (AAD/NPF [Menter 2019]).
- Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur; may require hospitalization. Discontinue use and initiate appropriate therapy if serious hypersensitivity reactions occur.
- Infections: Guselkumab may increase the risk of infections; upper respiratory tract infections, gastroenteritis, tinea infections, and herpes simplex infections have occurred more frequently. Consider the risks versus benefits prior to treatment initiation in patients with a history of chronic or recurrent infection; treatment should not be initiated in patients with clinically important active infections until it is resolved or treated. Monitor for infections; patients should seek medical attention for signs/symptoms of a clinically important infection (acute or chronic). If a serious infection develops or is unresponsive to appropriate therapy for the infection, monitor closely and discontinue guselkumab until the infection resolves.
- Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy. Do not administer to patients with an active TB infection. Treatment for latent TB should be administered prior to administering guselkumab. Consider anti-TB therapy prior to treatment initiation in patients with a history of latent or active TB in whom an adequate course of TB treatment cannot be confirmed. Monitor closely for signs/symptoms of active TB during and after guselkumab treatment.
- Immunizations: Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently; there are no data available concerning secondary transmission of infection by live vaccines in patients receiving therapy.

References:

9. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2019;80(4):1029-1072.
10. Singh JA, Guyatt G, Ogdie A, et al. 2018 american college of rheumatology/national psoriasis foundation guideline for the treatment of psoriatic arthritis. Arthritis & Rheumatology. 2019;71(1):5-32.

MedOne P&T Committee approval: Date: 1-1-17

Adopted:	1-1-17
Revised:	10-27-2022
10-27-21	3. Grandfathering criteria requirements explained 4. Pricing updated based off of AWP 5. Noted special considerations 6. Added scalp to sensitive areas for plaque psoriasis
Effective Date (most recent revisions):	12-12-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*