COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: June 1, 2022 Notification Posted: April 15, 2022

CONTENTS	PAGE

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

NEW UM PROGRAM CRITERIA			
Lybalvi PA			
Program Type:	☒ Prior Authorization	☐ Quantity Limit	☐ Step Therapy

medOne Pharmacy Benefit Solutions

Prior Authorization Approval Criteria

Lybalvi (olanzapine-samidorphan L-malate)

Generic name:	olanzapine-samidorphan L-malate	
Brand name:	Lybalvi	
Medispan GPI:	6299480250****	MONY
Medication class:	Second Generation Atypical Antipsychotic	
FDA-approved uses:	**Bipolar I Disorder** **Schizophrenia**	
Usual dose range:		
Bipolar I – monotherapy	Initial: Olanzapine 10 mg/samidorphan 10 mg or olanzapine 15 mg/samidorphan 10 mg once daily.	Maximum: Olanzapine 20 mg/samidorphan 10 mg once daily.
Bipolar I – adjunctive therapy to lithium or valproate	Initial: Olanzapine 10 mg/samidorphan 10 mg once daily.	Maximum: Olanzapine 20 mg/samidorphan 10 mg once daily.
Schizophrenia	Initial: Olanzapine 5 mg/samidorphan 10 mg or olanzapine 10 mg/samidorphan 10 mg once daily.	Maximum: Olanzapine 20 mg/samidorphan 10 mg once daily.

The criteria listed above applies to MedOne Clinical Review Program

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: $20,294 per patient per year AWP

Criteria for use for Bipolar I Disorder

- 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.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Lybalvi (as evidenced by coverage effective date of less than or equal to 120 days)
    - Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure, contraindication, or intolerance to 2 preferred generic antipsychotics:
    - Aripiprazole (Abilify)
    - Chlorpromazine (Thorazine)
    - Clozapine (Clozaril)
    - Fluphenazine (Prolixin)
    - Haloperidol (Haldol)
    - Loxapine (Loxitane)
    - Olanzapine (Zyprexa)
    - Paliperidone (Invega)
    - Pimozide (Orap)
    - Quetiapine IR/ER (Seroquel)
    - Risperidone (Risperdal)
    - Thiothixene (Navane)
    - Trifluoperzine (Stelazine)
    - Ziprasidone (Geodon)

  -AND-
- Patient has failure, contraindication, or intolerance to 1 preferred brand antipsychotics:
    - Latuda (lurasidone)
    - Rexulti (brexpiprazole)
    - Vraylar (cariprazine)

  -OR-
- Treatment with Lybalvi was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

Criteria for use for Schizophrenia

- 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.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Lybalvi (as evidenced by coverage effective date of less than or equal to 120 days)
    - Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure, contraindication, or intolerance to 2 preferred generic antipsychotics:
    - Aripiprazole (Abilify)
    - Chlorpromazine (Thorazine)
    - Clozapine (Clozaril)
    - Fluphenazine (Prolixin)
    - Haloperidol (Haldol)
    - Loxapine (Loxitane)
    - Olanzapine (Zyprexa)
    - Paliperidone (Invega)
    - Pimozide (Orap)
    - Quetiapine IR/ER (Seroquel)
    - Risperidone (Risperdal)
    - Thiothixene (Navane)
    - Trifluoperzine (Stelazine)
    - Ziprasidone (Geodon)

  -AND-
- Patient has failure, contraindication, or intolerance to 1 preferred brand antipsychotics:
    - Latuda (lurasidone)
    - Rexulti (brexpiprazole)
    - Vraylar (cariprazine)

  -OR-
- Treatment with Lybalvi was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

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%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Concomitant use with opioids
- Patients undergoing acute opioid withdrawal

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient is less than 18, safety and effectiveness not established in pediatric patients.

Special Considerations:

- In patients with impaired renal function (eGFR 15 to 29 mL/minute/1.73 m2) - No dosage adjustment necessary; however, use caution (increased exposure in patients with severe renal impairment).
- In patients with end stage renal disease, use is not recommended (has not been studied)
- In patients with impaired hepatic function - no dosage adjustment necessary; however, use caution (increased exposure in patients with moderate hepatic impairment).
- Patients with a history of chronic opioid use prior to olanzapine/samidorphan therapy may respond to lower opioid doses than previously used if therapy is interrupted or discontinued; may increase the risk of opioid overdose if resumed at previously tolerated dose. Warn patients that any attempt to overcome opioid blockade during olanzapine/samidorphan therapy is dangerous and could potentially lead to life-threatening opioid intoxication (eg, respiratory arrest, circulatory collapse). If opioid therapy is required as part of anesthesia or analgesia, discontinue olanzapine/samidorphan and monitor closely.
- Olanzapine may cause anticholinergic effects (eg, constipation, xerostomia, blurred vision, urinary retention, tachycardia); use with caution in patients with decreased gastrointestinal motility, urinary retention, or benign prostatic hyperplasia. Relative to other neuroleptics, olanzapine has a moderate potency of cholinergic blockade.
- Leukopenia, neutropenia, and agranulocytosis (sometimes fatal) have been reported in clinical trials and postmarketing reports with antipsychotic use; presence of risk factors (eg, preexisting low WBC or history of drug-induced leukopenia/neutropenia) should prompt periodic blood count assessment. Discontinue therapy at first signs of blood dyscrasias or if absolute neutrophil count <1,000/mm3.
- An increased incidence of cerebrovascular effects (eg, transient ischemic attack, stroke), including fatalities, has been reported in placebo-controlled trials of olanzapine for the unapproved use in elderly patients with dementia-related psychosis.
- Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with olanzapine; may be fatal. Symptoms of DRESS include cutaneous reaction (rash or exfoliative dermatitis), fever, lymphadenopathy, eosinophilia, and systemic complications (eg, hepatitis, nephritis, pneumonitis, myocarditis, pericarditis); discontinue use if DRESS is suspected.
- Antipsychotic use has been associated with esophageal dysmotility and aspiration; risk increases with age. Use with caution in patients at risk for aspiration pneumonia (eg, Alzheimer disease), particularly in patients >75 years of age.
- Olanzapine may cause extrapyramidal symptoms (EPS), including pseudoparkinsonism, acute dystonic reactions, akathisia, and tardive dyskinesia (risk of these reactions is generally much lower relative to typical/conventional antipsychotics; frequencies are similar to placebo). Risk of dystonia (and probably other EPS) may be greater with increased doses, use of conventional antipsychotics, males, and younger patients. Factors associated with greater vulnerability to tardive dyskinesia include older in age, female gender combined with postmenopausal status, Parkinson disease, pseudoparkinsonism symptoms, affective disorders (particularly major depressive disorder), concurrent medical diseases, such as diabetes, previous brain damage, alcoholism, poor treatment response, and use of high doses of antipsychotics. Consider therapy discontinuation with signs/symptoms of tardive dyskinesia.
- Olanzapine may increase the risk for falls due to somnolence, orthostatic hypotension, and motor or sensory instability.

References:

1. Lybalvi (olanzapine and samidorphan) [prescribing information]. Waltham, MA: Alkermes Inc; May 2021
2. Herzig SJ, LaSalvia MT, Naidus E, et al. Antipsychotics and the risk of aspiration pneumonia in individuals hospitalized for nonpsychiatric conditions: a cohort study. J Am Geriatr Soc. 2017;65(12):2580-2586. doi:10.1111/jgs.15066[PubMed 29095482]
3. Maddalena AS, Fox M, Hofmann M, Hock C. Esophageal dysfunction on psychotropic medication. A case report and literature review. Pharmacopsychiatry. 2004;37(3):134-138. doi:10.1055/s-2004-818993[PubMed 15138897]
4. Keepers GA, Fochtmann LJ, Anzia JM, et al; (Systematic Review). The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. Am J Psychiatry. 2020;177(9):868-872. doi:10.1176/appi.ajp.2020.177901[PubMed 32867516]
5. Soares-Weiser K, Fernandez HH. Tardive dyskinesia. Semin Neurol. 2007;27(2):159-169. doi:10.1055/s-2007-971169[PubMed 17390261]

MedOne P&T Committee approval: Date: 4-4-22

Initial adoption: 4-4-22
Revised:

Effective Date (most recent revisions): 6-1-22

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

UM PROGRAM CRITERIA REVISED	
Taltz PA	
Program Type: ☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy	
Taltz	1. Ankylosing Spondylitis and Axial spondyloarthritis added as indications. 2. Pricing updated based off of AWP (4/7/22). 3. Added pediatric dosing for plaque psoriasis indication. 4. Added initial and maintenance dosing for AS, Axial spondyloarthritis, and Psoriatic arthritis. 5. Added fail first criteria for Ankylosing Spondylitis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to one of the following Cosentyx, Humira, Enbrel. 6. Added fail first criteria for Nonradiographic axial spondyloarthritis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to Cosentyx. 7. Updated fail first criteria for Plaque Psoriasis and Psoriatic arthritis to include failure, intolerance, or contraindication to at least ONE conventional systemic DMARD -AND- At least TWO category B medications.

Prior Authorization Approval Criteria

Taltz (ixekizumab)

Generic name: ixekizumab
Brand name: Taltz
Medispan GPI: 9025055400**** MON
Medication class: Antipsoriatic Agent; Anti-interleukin 17A monoclonal antibody
FDA-approved uses: **Ankylosing Spondylitis (AS)**
Nonradiographic axial spondyloarthritis
Plaque Psoriasis (PsO)
Psoriatic Arthritis (PsA)

Usual dose range:

AS	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks
Axial spondyloarthritis	Initial: not indicated	Maintenance: 80 mg every 4 weeks
Plaque psoriasis	Initial: 160 mg once followed by 80 mg at weeks 2,4,6,8,10 and 12	Maintenance: 80 mg every 4 weeks
Plaque psoriasis Pediatric		
<25 kg	Initial: 40 mg once	Maintenance: 20 mg every 4 weeks
25-50 kg	Initial: 80 mg once	Maintenance: 40 mg every 4 weeks
>50 kg	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks
Psoriatic arthritis	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks

Duration of Authorization:

Initial:	4 months
Ongoing:	12 months

Estimated Cost: $7,527 80mg/mL dose ($112,905-127,959) (range dependent on use of loading dose)

Criteria for use for Ankylosing Spondylitis

- 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.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- 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
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccinescannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has failure, contraindication, or intolerance to at least one prescription strength formulary NSAID.
- Documentation of an adequate trial and failure/intolerance of at least one conventional systemic or non-biologic DMARD is encouraged but not required.
  -AND-
- Patient has failure, contraindication, or intolerance to one of the following Cosentyx, Humira, Enbrel

Criteria for use for Nonradiographic axial spondyloarthritis

- 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.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- 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
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has documented failure (active condition despite 3 months of treatment), contraindication, or intolerance to each of the following for their respective indications: methotrexate, cyclosporine, acitretin, leflunomide, or sulfasalazine
- Patient has failure, contraindication, or intolerance to at least one prescription strength formulary NSAID.
- Documentation of an adequate trial and failure/intolerance of at least one conventional systemic or non-biologic DMARD is encouraged but not required
  -AND-
- Patient has failure, contraindication, or intolerance to Cosentyx

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 an approved indication.
- Must be 6 years of age or older. Went from 12 to 6
- 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
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Dermatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has failure, contraindication, or intolerance to at least one conventional systemic DMARD (acitretin, cyclosporine, methotrexate, sulfasalazine).
- Patient must be a candidate for phototherapy or systemic therapy
- Patient must have 10% or more BSA involvement OR involvement of a sensitive area (hands, feet, face, scalp, or genital area)
- 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, Skyrizi).

Criteria for use for Psoriatic arthritis

- 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.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- 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
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist or Dermatologist. Consult note (documentation of recommendation) must be provided if recommendation was in consultation with specialist.
- Patient must have failure, intolerance, or contraindication to at least ONE conventional systemic DMARD (azathioprine, hydroxychloroquine, methotrexate, leflunomide)
  -AND-
- At least TWO category B medications (Humira, Enbrel, Cosenytx, Stelara, Xeljanz/Xeljanz XR)

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%.

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:

- Treatment with ixekizumab may cause or exacerbate Crohn's and Ulceractive Colitis. Patients should be monitored for signs/symptoms of inflammatory bowel disease.
- Infections: May increase the risk of infections. A higher rate of infections was observed with ixekizumab treatment in clinical trials, including upper respiratory tract infection, oral candidiasis, conjunctivitis, and tinea infections. Use with caution in patients with a chronic infection or a history of recurrent infection. In patients who develop a serious infection, monitor closely and discontinue use until the infection resolves.
- Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy; do not initiate therapy in patients with an active TB infection. Consider antituberculosis therapy if an adequate course of treatment cannot be confirmed in patients with a history of latent or active TB. Monitor all patients for signs and symptoms of active TB during and after treatment.
- Immunizations: Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently.

References:

1. Taltz ® [package insert]. Indianapolis, IN: Eli Lilly and Co.; March 2016. Revised November 2021.
2. Farahnik B, Beroukhim K, Nakamura M, Abrouk M, Zhu TH, Singh R, Lee K, Bhutani T, Koo J. Anti-IL-17 Agents for Psoriasis: A Review of Phase III Data. J Drugs Dermatol. 2016 Mar 1;15(3):311-6.
3. Genovese MC, Braun DK, Erickson JS, Berclaz PY, Banerjee S, Heffernan MP, Carlier H. Safety and Efficacy of Open-label Subcutaneous Ixekizumab Treatment for 48 Weeks in a Phase II Study in Biologic-naive and TNF-IR Patients with Rheumatoid Arthritis. J Rheumatol. 2016Feb;43(2):289-97.
4. Leonardi CL, Kimball AB, Papp KA, et al: Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). Lancet 2008; 371(9625):1665-1674.
5. Papp KA, Langley RG, Lebwohl M, et al: Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). Lancet 2008; 371(9625):1675-1684.
6. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. J Am Acad Dermtol. 2010;65(1):137-174.

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

Initial adoption: 1/1/17

Revised: 4/7/22

1. Ankylosing Spondylitis and Axial spondyloarthritis added as indications.
2. Pricing updated based off of AWP (4/7/22).
3. Added pediatric dosing for plaque psoriasis indication.
4. Added initial and maintenance dosing for AS, Axial spondyloarthritis, and Psoriatic arthritis.
5. Added fail first criteria for Ankylosing Spondylitis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to one of the following Cosentyx, Humira, Enbrel.
6. Added fail first criteria for Nonradiographic axial spondyloarthritis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to Cosentyx.
7. Updated fail first criteria for Plaque Psoriasis and Psoriatic arthritis to include failure, intolerance, or contraindication to at least ONE conventional systemic DMARD -AND- At least TWO category B medications.

Effective Date (most recent revisions): 6/1/2022

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