COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 3/1/2023 Notification Posted: 1/13/2023

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

UM PROGRAM CRITERIA REVISED			
Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Biktarvy	1. Pricing updated based off of AWP (1-10-23) 2. Updated CD4 requirements to make optional reporting with stable labs. 3. Require infectious disease or HIV specialist for HIV diagnosis.		

Prior Authorization Approval Criteria

Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)

Generic name: bictegravir, emtricitabine, and tenofovir alafenamide
Brand name: Biktarvy
Medispan GPI: 121099022903** MON
Medication class: Combination antiretroviral / Nucleoside Reverse Transcriptase Inhibitor & Integrase Strand Transfer Inhibitor
FDA-approved uses: **HIV Infection**

Usual dose range:
HIV - adult bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg (1 tablet) orally daily
HIV - pediatric See below

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost:

$55,410.53 annual (AWP)

Criteria for use for HIV

- 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 HIV-1 infection.
- Must be prescribed by or following a consultation with an infectious disease prescriber or HIV specialist.
- Clinical documentation of the following labs within the previous 12 months:
    - CD4 labs
    - HIV viral load/viral RNA
    - eGFR (initial use)
    - Hepatitis B screening (initial use)
- Pediatric patients must weigh no less than 14kg
    - Weight 14 to <25 kg: Bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg per tablet once daily.
        - Note: In clinical trials evaluating this dose, the youngest patients were 3 years of age.
    - Weight ≥25 kg: Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg per tablet once daily.

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 current CD4 labs and HIV viral load/viral RNA (since last approval).
    - CD4 counts could be considered optional, if after 2 years of ART with consistently suppressed viral load, and:
        - CD4 count 300-500 cells/mm^3 = every 12-month recheck
        - CD4 count >500 cells/mm^3 = optional
    - Visit notes are not required, completed and signed form will suffice as documentation.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Coadministration with dofetilide, rifampin.

Not approved if:

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

Special Considerations:

- In patients with impaired renal function for the treatment of HIV:
    - CrCl <30 mL/minute: Use is not recommended.

- Hemodialysis: One tablet (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg) once daily; administer after hemodialysis on dialysis days.

- Patients may develop immune reconstitution syndrome resulting in the occurrence of an inflammatory response to an indolent or residual opportunistic infection during initial HIV treatment or activation of autoimmune disorders (eg, Graves disease, polymyositis, Guillain-Barré syndrome, autoimmune hepatitis) later in therapy; further evaluation and treatment may be required.
- Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).

References:

1. Biktarvy (bictegravir, emtricitabine, tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences; November 2022.
2. US Department of Health and Human Services (HHS). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016. https://stacks.cdc.gov/view/cdc/38856
3. US Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. HIV.gov. Updated January 20, 2022. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines
4. US Department of Health and Human Services (HHS) Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the use of antiretroviral agents in pediatric HIV infection. HIV.gov. Updated April 11, 2022. https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new-guidelines
5. US Department of Health and Human Services (HHS) Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Updated December 30, 2021.

MedOne Clinical Review Subcommittee approval: Date: 1-1-17

Initial adoption:	1-1-17
Revised:	1-10-23
1-10-23	1. Pricing updated based off of AWP (1-10-23) 2. Updated CD4 requirements to make optional reporting with stable labs. 3. Require infectious disease or HIV specialist for HIV diagnosis.
Effective Date (most recent revisions):	3-1-2023

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

UM PROGRAM CRITERIA REVISED			
Descovy (emtricitabine/tenofovir alafenamide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Descovy	1. Pricing updated based off of AWP (1-10-23) 2. Updated CD4 requirements to make optional reporting with stable labs. 3. Require infectious disease or HIV specialist for HIV diagnosis.		

Prior Authorization Approval Criteria

Descovy
(emtricitabine/tenofovir alafenamide)

Generic name: emtricitabine/tenofovir alafenamide
Brand name: Descovy
Medispan GPI: 121099022903** MON
Medication class: Combination antiretroviral / Nucleoside Reverse Transcriptase Inhibitor
FDA-approved uses: **HIV Infection**
HIV Preexposure Prophylaxis (PrEP)

Usual dose range:
HIV - adult Emtricitabine 200 mg/tenofovir alafenamide 25 mg (1 tablet) orally daily
HIV - pediatric See below
PrEP Emtricitabine 200 mg/tenofovir alafenamide 25 mg (1 tablet) orally daily

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost:
$31,523.11 annual (AWP)

Criteria for use for HIV

- 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 HIV-1 infection.
- Must be prescribed by or following a consultation with an infectious disease prescriber or HIV specialist.
- Clinical documentation of the following labs within the previous 12 months:
  - CD4 labs
  - HIV viral load/viral RNA
  - eGFR (initial use)
  - Hepatitis B screening (initial use)
- Pediatric patients must weigh no less than 14kg
  - (14 to less than 25 kg) Emtricitabine 120 mg/tenofovir alafenamide 15 mg as one tablet orally daily
  - (25 kg to less than 35 kg) Emtricitabine 200 mg/tenofovir alafenamide 25 mg as one tablet orally daily
  - (At least 35 kg) Emtricitabine 200 mg/tenofovir alafenamide 25 mg as one tablet orally daily

Criteria for use for HIV PrEP

- 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 and weighing greater than or equal to 35kg (77 lb).
- Grandfather criteria allowed
- Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Any available provider
- Patient is using in combination with safer sex practices for preexposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. High risk defined as:
    - high risk sexual activity
    - inconsistent condom use
    - diagnosed with STD in past 6 months
    - share needles, syringes, or other equipment to inject drugs.
- Patient must have a confirmed negative HIV-1 test 1 month prior to starting PrEP and retest every 3 months while patient receives PrEP as noted in current CDC guidelines.
- Patient trialed and failed generic emtricitabine/tenofovir disoproxil fumarate (generic Truvada)
- For renal or bone density contraindication requests, documentation of:
    - current estimated glomerular filtration rate (eGFR) below 90 mL/min
    - a diagnosis of osteoporosis as defined by a BMD T-score ≤ -2.5
    - a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5

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 current CD4 labs and HIV viral load/viral RNA (since last approval).
    - CD4 counts could be considered optional, if after 2 years of ART with consistently suppressed viral load, and:
        - CD4 count 300-500 cells/mm^3 = every 12-month recheck
        - CD4 count >500 cells/mm^3 = optional
    - Visit notes are not required, completed and signed form will suffice as documentation.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- As preexposure prophylaxis in patients with unknown or HIV-1 positive status.

Not approved if:

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

Special Considerations:

- In patients with impaired renal function for the treatment of HIV:
    - CrCl <30 mL/minute: Use is not recommended.
    - Hemodialysis: intermittent (thrice weekly): One tablet (emtricitabine 200 mg/tenofovir alafenamide 25 mg) once daily; when scheduled dose falls on a dialysis day, administer after hemodialysis

- Patients may develop immune reconstitution syndrome resulting in the occurrence of an inflammatory response to an indolent or residual opportunistic infection during initial HIV treatment or activation of autoimmune disorders (eg, Graves disease, polymyositis, Guillain-Barré syndrome, autoimmune hepatitis) later in therapy; further evaluation and treatment may be required.
- Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).
- Preexposure prophylaxis (PrEP) should be accompanied by a comprehensive HIV-1 prevention program (eg, risk reduction counseling, access to condoms), with particular emphasis on medication adherence. In addition, regular monitoring (eg, HIV status of patient and partner(s), risk behavior, adherence, adverse effects, sexually transmitted infections that facilitate HIV-1 transmission) is highly recommended. Time from initiation of therapy to maximal protection against HIV-1 is unknown.

References:

6. Descovy (emtricitabine and tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences Inc; January 2022.
7. US Department of Health and Human Services (HHS). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016. https://stacks.cdc.gov/view/cdc/38856
8. US Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. HIV.gov. Updated January 20, 2022. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines
9. US Department of Health and Human Services (HHS) Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the use of antiretroviral agents in pediatric HIV infection. HIV.gov. Updated April 11, 2022. https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new-guidelines
10. US Department of Health and Human Services (HHS) Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Updated December 30, 2021.

MedOne Clinical Review Subcommittee approval: Date: 1-1-17

Initial adoption: 1-1-17
Revised: 1-10-23
1-10-23
4. Pricing updated based off of AWP (1-10-23)
5. Updated CD4 requirements to make optional reporting with stable labs.
6. Require infectious disease or HIV specialist for HIV diagnosis.

Effective Date (most recent revisions): 3-1-2023

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

adopted this clinical policy and that is operated or administered, in whole or in part, by MedOne Pharmacy Benefits, or any of such health plan's affiliates, as applicable.

UM PROGRAM CRITERIA REVISED			
Forteo (teriparatide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Forteo	1. Pricing updated based off of AWP (8-15-22) 2. Updated fail first criteria from 2 to 1 oral bisphosphonate if treatment failure, 2 if intolerance 3. Added Prolia trial requirement 4. Added max 24 month duration and updated initial duration from 6 to 12 months 5. Added requirement to use as monotherapy 6. Added "Y" to Medispan parameters		

Prior Authorization Approval Criteria

Forteo (teriparatide)

Generic name: teriparatide
Brand name: Forteo
Medispan GPI: 3004407000**** MONY
Medication class: Parathyroid Hormone Analog
FDA-approved uses: **Osteoporosis, postmenopausal, fracture risk reduction**
Primary or hypogonadal osteoporosis in men who are at high risk for fracture
Glucocorticoid-induced osteoporosis at high risk for fracture (men and women)

Usual dose range:

Osteoporosis, fracture risk reduction (male and female)	20 mcg subcutaneously once daily
Glucocorticoid-induced osteoporosis	20mcg subcutaneously once daily

Duration of Authorization:

Initial: 12 months
Ongoing: Up to 1 year not to exceed 24 months of total cumulative treatment
*Duration of teriparatide therapy should generally not exceed 2 years due to limited data with use beyond this; fracture reduction efficacy has been demonstrated over a period of 18 to 24 months.

Estimated Cost: $4759.93 per 600mcg/2.4mL pen (30 day supply) AWP

Criteria for use for Osteoporosis, postmenopausal, fracture risk reduction

- 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 postmenopausal osteoporosis with:
    - BMD T-score ≤ -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) in the absence of a fracture
      -OR-
        - BMD T-score between -3.5 and -2.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
          -AND-
            - Patient must have documented history of one of the following fragility fractures resulting from minimal trauma:
                - Vertebral compression fracture
                - Fracture of the hip
                - Fracture of the distal radius
                - Fracture of the pelvis
                - Fracture of the proximal humerus

          -OR-
            - Patient has a FRAX 10-year fracture probability of ≥20% for major osteoporotic fracture or ≥3% for hip fracture

      -AND-
- Patient has clinical failure of **ONE**, or contraindication / intolerance to at least **TWO** oral or injectable bisphosphonates
    - Trial of injectable bisphosphonate is required in patients unable to take oral bisphosphonates due to a contraindication specific only to oral bisphosphonates (swallowing difficulties, esophageal motility disorders, inability to stand or sit upright for ≥30 minutes, increased risk of aspiration)
    - Failure is defined as a non-traumatic fracture while on bisphosphonate therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Patient has clinical failure, contraindication, or intolerance to treatment with Prolia
    - Failure is defined as a non-traumatic fracture while on Prolia therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
        - Post-menopausal women with high risk for vertebral fractures (as defined above) or with history of previous vertebral fractures are exempt from requirement to try/fail both bisphosphonates and Prolia
- Use of Forteo will not be used concurrently with other medications for osteoporosis, such as Tymlos (abaloparatide), Prolia (denosumab), bisphosphonates, calcitonin, teriparatide, etc.
- Treatment duration has not exceeded a total of 24 months of cumulative use of any parathyroid hormone analogs

Criteria for use for Primary or hypogonadal osteoporosis in men who are at high risk for fracture

- 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 primary or hypogonadal osteoporosis in men who are at high risk for fracture:
    - BMD T-score ≤ -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
      -OR-
        - BMD T-score between -3.5 and -2.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)

-AND-

- Patient must have documented history of one of the following resulting from minimal trauma:
  - Vertebral compression fracture
  - Fracture of the hip
  - Fracture of the distal radius
  - Fracture of the pelvis
  - Fracture of the proximal humerus

-OR-

- Patient has a FRAX 10-year fracture probability of ≥20% for major osteoporotic fracture or ≥3% for hip fracture

-AND-

- Patient has clinical failure of ONE, or contraindication / intolerance to at least TWO oral or injectable bisphosphonates
  - Trial of injectable bisphosphonate is required in patients unable to take oral bisphosphonates due to a contraindication specific only to oral bisphosphonates (swallowing difficulties, esophageal motility disorders, inability to stand or sit upright for ≥30 minutes, increased risk of aspiration)
  - Failure is defined as a non-traumatic fracture while on bisphosphonate therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Patient has clinical failure, contraindication, or intolerance to treatment with Prolia
  - Failure is defined as a non-traumatic fracture while on Prolia therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Use of Forteo will not be used concurrently with other medications for osteoporosis, such as Tymlos (abaloparatide), Prolia (denosumab), bisphosphonates, calcitonin, teriparatide, etc.
- Treatment duration has not exceeded a total of 24 months of cumulative use of any parathyroid hormone analogs

Criteria for use for Glucocorticoid-induced osteoporosis at high risk for fracture

- 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 glucocorticoid-induced osteoporosis with:
  - BMD T-score ≤ -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)

    -OR-

    - BMD T-score between -3.5 and -2.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)

      -AND-

      - Patient must have documented history of one of the following resulting from minimal trauma:
        - Vertebral compression fracture
        - Fracture of the hip
        - Fracture of the distal radius
        - Fracture of the pelvis
        - Fracture of the proximal humerus

      -OR-

      - Patient has a FRAX 10-year fracture probability of ≥20% for major osteoporotic fracture or ≥3% for hip fracture

    -AND-

- Patient has clinical failure of ONE, or contraindication / intolerance to at least TWO oral or injectable bisphosphonates
    - Trial of injectable bisphosphonate is required in patients unable to take oral bisphosphonates due to a contraindication specific only to oral bisphosphonates (swallowing difficulties, esophageal motility disorders, inability to stand or sit upright for ≥30 minutes, increased risk of aspiration)
    - Failure is defined as a non-traumatic fracture while on bisphosphonate therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Patient has clinical failure, contraindication, or intolerance to treatment with Prolia
    - Failure is defined as a non-traumatic fracture while on Prolia therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Use of Forteo will not be used concurrently with other medications for osteoporosis, such as Tymlos (abaloparatide), Prolia (denosumab), bisphosphonates, calcitonin, teriparatide, etc.
- Treatment duration has not exceeded a total of 24 months of cumulative use of any parathyroid hormone analogs

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. Summitted 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%.
- Total duration of use is less than 24 months of therapy.

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 is premenopausal.

Special Considerations:

- Ensure adequate calcium and vitamin D intake; if dietary intake is inadequate, dietary supplementation is recommended. Patients should consume:
    - Calcium: 1,000 mg/day (males: 50 to 70 years of age) or 1,200 mg/day (females ≥51 years of age and males ≥71 years of age)
    - Vitamin D: 800 to 1,000 units/day (age ≥50 years) (NOF [Cosman 2014]). Recommended dietary allowance (RDA): 600 units/day (age ≤70 years) or 800 units/day (age ≥71 years)
- Serious worsening of previous stable cutaneous calcification or calciphylaxis has been reported; discontinue use if occurs. Patients with underlying autoimmune disease, kidney failure, or concomitantly taking warfarin or systemic corticosteroids are at increased risk.
- May cause orthostatic hypotension. Transient orthostatic hypotension usually occurs within 4 hours of dosing and within the first several doses; usually resolved without treatment within a few minutes to a few hours.
- In animal studies, teriparatide has been associated with an increase in osteosarcoma. Human cases have been reported in postmarketing; increased risk has not been seen in observational studies. Avoid use in patients with an increased risk of osteosarcoma (including Paget disease, bone metastases or a history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, hereditary disorders predisposing to osteosarcoma, or in patients with open epiphyses).

References:

1. Forteo (teriparatide) [prescribing information]. Indianapolis, IN: Lilly USA LLC; September 2021.
2. IOM (Institute of Medicine). Dietary Reference Intakes for Calcium and Vitamin D. The National Academies Press; 2011.
3. Rosen HN, Drezner MK. Overview of the management of osteoporosis in postmenopausal women. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.
4. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019;104(5):1595-1622. doi:10.1210/jc.2019-00221[PubMed 30907953]
5. Liu CL et al. Head-to-head comparisons of bisphosphonates and teriparatide in osteoporosis: a meta-analysis. Clin Invest Med 2017; 40(3):E146-E157.
6. Leder BZ et al. Two years of Denosumab and teriparatide administration in postmenopausal women with osteoporosis (The DATA Extension Study): A randomized controlled trial. J Clin Endocrinol Metab 2014;99(5):1694-1700.
7. The Journal of The North American Menopause Society.28(9),973-997
8. J Clin Endocrinol Metab, May 2019,104(5):1595–1622

MedOne P&T Committee approval: Date: 12-21-2002

Initial adoption:	12-1-2002
Revised:	8-15-22
	12-21-22
	1-13-23
8-15-22	Pricing updated based off of AWP (8-15-22) Updated fail first criteria from 2 to 1 oral bisphosphonate if treatment failure, 2 if intolerance Added Prolia trial requirement Added max 24 month duration and updated initial duration from 6 to 12 months Added requirement to use as monotherapy Added "Y" to Medispan parameters
12-21-22	Removed requirement to fail both bisphosphonates and Prolia for high-risk menopausal women Clinical review/studies added to references
1-13-23	Updated glucocorticoid-induced section to corrected required diagnosis.
Effective Date (most recent revisions):	3-1-2023

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

UM PROGRAM CRITERIA REVISED			
Truvada (emtricitabine/tenofovir disoproxil fumarate)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Truvada	1. Pricing updated based off of AWP (1-10-23) 2. Updated CD4 requirements to make optional reporting with stable labs. 3. Require infectious disease or HIV specialist for HIV diagnosis.		

Prior Authorization Approval Criteria

Truvada

(emtricitabine/tenofovir disoproxil fumarate)

Generic name: emtricitabine/tenofovir disoproxil fumarate
Brand name: Truvada
Medispan GPI: 121099023003** MONY
Medication class: Combination antiretroviral / Nucleoside Reverse Transcriptase Inhibitor
FDA-approved uses: **HIV Infection**
HIV Preexposure Prophylaxis (PrEP)
HIV Postexposure Prophylaxis (PEP)

Usual dose range:

HIV - adult	Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (1 tablet) orally daily
HIV - pediatric	See below
PrEP	Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (1 tablet) orally daily
PEP	Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (1 tablet) orally daily for 28 days

Duration of Authorization:

Initial:	4 months
Ongoing:	12 months

Estimated Cost:

Brand	$26,897.59 annual (AWP)
Generic	$4390.42 annual (MEDONEMAC)
PEP (generic)	$336.80 28-day supply (MEDONEMAC)

Criteria for use for HIV

- 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 HIV-1 infection.
- Must be prescribed by or following a consultation with an infectious disease prescriber or HIV specialist.
- Clinical documentation of the following labs within the previous 12 months:
  - CD4 labs
  - HIV viral load/viral RNA

    - eGFR (initial use)
    - Hepatitis B screening (initial use)
- Pediatric patients must weigh no less than 17kg
    - (17 to less than 22 kg) Emtricitabine 100 mg/tenofovir disoproxil fumarate 150 mg (1 tablet) orally daily
    - (22 to less than 28 kg) Emtricitabine 133 mg/tenofovir disoproxil fumarate 200 mg (1 tablet) orally daily
    - (28 to less than 35 kg) Emtricitabine 167 mg/tenofovir disoproxil fumarate 250 mg (1 tablet) orally daily
    - (35 kg or greater) Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (1 tablet) orally daily

Criteria for use for HIV PrEP

- 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 and weighing greater than or equal to 35kg (77 lb).
- Grandfather criteria allowed
- Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is using in combination with safer sex practices for preexposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. High risk defined as
    - high risk sexual activity
    - inconsistent condom use
    - diagnosed with STD in past 6 months
    - share needles, syringes, or other equipment to inject drugs.
- Patient must have a confirmed negative HIV-1 test 1 month prior to starting PrEP and retest every 3 months while patient receives PrEP as noted in current CDC guidelines.

Criteria for use for HIV PEP

- 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 HIV negative or do not know their HIV status, and who in the last 72 hours: may have been exposed to HIV during sex, were sexually assaulted, shared needles or other equipment (works) to inject drugs.
- Authorization will be for 28 days and will be in combination with either Isentress or Tivicay.

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 current CD4 labs and HIV viral load/viral RNA (since last approval).
    - CD4 counts could be considered optional, if after 2 years of ART with consistently suppressed viral load, and:
        - CD4 count 300-500 cells/mm^3 = every 12-month recheck
        - CD4 count >500 cells/mm^3 = optional
    - Visit notes are not required, completed and signed form will suffice as documentation.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- As preexposure prophylaxis in patients with unknown or HIV-1 positive status.

Not approved if:

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

Special Considerations:

- In adult patients with impaired renal function for the treatment of HIV:
  - CrCl 30 to 49 mL/minute: Increase interval to every 48 hours.
  - CrCl <30 mL/minute: Not recommended.
  - Hemodialysis: Not recommended.
- In adult patients with impaired renal function for PrEP:
  - CrCl <60 mL/minute: Not recommended.
- In pediatric patients with altered renal function, there are no pediatric-specific recommendations; based on experience in adult patients, dosage adjustment suggested; use in hemodialysis is not recommended.
- Patients may develop immune reconstitution syndrome resulting in the occurrence of an inflammatory response to an indolent or residual opportunistic infection during initial HIV treatment or activation of autoimmune disorders (eg, Graves disease, polymyositis, Guillain-Barré syndrome, autoimmune hepatitis) later in therapy; further evaluation and treatment may be required.
- Lactic acidosis and severe hepatomegaly with steatosis, sometimes fatal, have been reported with use of nucleoside analogues, alone or in combination with other antiretrovirals. Suspend treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (marked transaminase elevation may/may not accompany hepatomegaly and steatosis).
- Preexposure prophylaxis (PrEP) should be accompanied by a comprehensive HIV-1 prevention program (eg, risk reduction counseling, access to condoms), with particular emphasis on medication adherence. In addition, regular monitoring (eg, HIV status of patient and partner(s), risk behavior, adherence, adverse effects, sexually transmitted infections that facilitate HIV-1 transmission) is highly recommended. Time from initiation of therapy to maximal protection against HIV-1 is unknown.

References:

11. Truvada (emtricitabine/tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences; June 2020.
12. US Department of Health and Human Services (HHS). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016. https://stacks.cdc.gov/view/cdc/38856
13. US Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. HIV.gov. Updated January 20, 2022. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines
14. US Department of Health and Human Services (HHS) Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the use of antiretroviral agents in pediatric HIV infection. HIV.gov. Updated April 11, 2022. https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new-guidelines
15. US Department of Health and Human Services (HHS) Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Updated December 30, 2021.

MedOne Clinical Review Subcommittee approval: Date: 1-1-17

Initial adoption: 1-1-17
Revised: 1-10-23
1-10-23
1. Pricing updated based off of AWP (1-10-23)
2. Updated CD4 requirements to make optional reporting with stable labs.
3. Require infectious disease or HIV specialist for HIV diagnosis.

Effective Date (most recent revisions): 3-1-2023

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

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UM PROGRAM CRITERIA REVISED			
Tymlos (abaloparatide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Tymlos	1. Pricing updated based off of AWP (8-15-22) 2. Updated fail first criteria from 2 to 1 oral bisphosphonate if treatment failure, 2 if intolerance 3. Added Prolia trial requirement 4. Added max 24 month duration and updated initial duration from 6 to 12 months 5. Added requirement to use as monotherapy		

Prior Authorization Approval Criteria

Tymlos (abaloparatide)

Generic name: abaloparatide
Brand name: Tymlos
Medispan GPI: 3004400500**** MON
Medication class: Parathyroid Hormone Analog
FDA-approved uses: **Osteoporosis, postmenopausal, fracture risk reduction**

Usual dose range:
Osteoporosis 80 mcg subcutaneously once daily

Duration of Authorization:
Initial: 12 months

Ongoing: Up to 1 year not to exceed 24 months of total cumulative treatment
*Duration of abaloparatide therapy should not exceed 2 years due to limited data with use beyond this; fracture reduction efficacy has been demonstrated over a period of 18 months.

Estimated Cost: $2747.21 per 3120mcg/1.56mL pen (30 day supply) AWP

Criteria for use for Osteoporosis

- 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 postmenopausal osteoporosis with:
    - BMD T-score ≤ -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
      -OR-
        - BMD T-score between -3.5 and -2.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
          -AND-
            - Patient must have documented history of one of the following resulting from minimal trauma:
                - Vertebral compression fracture
                - Fracture of the hip
                - Fracture of the distal radius
                - Fracture of the pelvis
                - Fracture of the proximal humerus

          -OR-
            - Patient has a FRAX 10-year fracture probability of ≥20% for major osteoporotic fracture or ≥3% for hip fracture

      -AND-
- Patient has clinical failure of ONE, or contraindication / intolerance to at least TWO oral or injectable bisphosphonates
    - Trial of injectable bisphosphonate is required in patients unable to take oral bisphosphonates due to a contraindication specific only to oral bisphosphonates (swallowing difficulties, esophageal motility disorders, inability to stand or sit upright for ≥30 minutes, increased risk of aspiration)
    - Failure is defined as a non-traumatic fracture while on bisphosphonate therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
- Patient has clinical failure, contraindication, or intolerance to treatment with Prolia
    - Failure is defined as a non-traumatic fracture while on Prolia therapy, -OR- inadequate response as evidenced by worsening BMD after at least 1 year of therapy, -OR- intolerable side effects
        - Post-menopausal women with high risk for vertebral fractures (as defined above) or with history of previous vertebral fractures are exempt from requirement to try/fail both bisphosphonates and Prolia
- Use of Tymlos will not be used concurrently with other medications for osteoporosis, such as Prolia (denosumab), bisphosphonates, calcitonin, teriparatide, etc.
- Treatment duration has not exceeded a total of 24 months of cumulative use of any parathyroid hormone analogs

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. Summitted 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%.
- Total duration of use is less than 24 months of therapy.

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 is premenopausal.

Special Considerations:

- Ensure adequate calcium and vitamin D intake; if dietary intake is inadequate, dietary supplementation is recommended. Patients should consume:
    - Calcium: 1,000 mg/day (males: 50 to 70 years of age) or 1,200 mg/day (females ≥51 years of age and males ≥71 years of age)
    - Vitamin D: 800 to 1,000 units/day (age ≥50 years) (NOF [Cosman 2014]). Recommended dietary allowance (RDA): 600 units/day (age ≤70 years) or 800 units/day (age ≥71 years)
- May cause or exacerbate hypercalcemia; use is not recommended in patients with preexisting hypercalcemia or with an underlying hypercalcemic disorder (eg, primary hyperparathyroidism).
- May cause orthostatic hypotension. Transient orthostatic hypotension usually occurs within 4 hours of dosing.
- In animal studies, abaloparatide has been associated with an increase in osteosarcoma; risk was dependent on both dose and duration. Avoid use in patients with an increased risk of osteosarcoma (including Paget disease, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, prior external beam or implant radiation therapy involving the skeleton, or in patients with open epiphyses).

References:

9. Tymlos (abaloparatide) [prescribing information]. Boston, MA: Radius Health Inc; December 2021.
10. IOM (Institute of Medicine). Dietary Reference Intakes for Calcium and Vitamin D. The National Academies Press; 2011.
11. Rosen HN, Drezner MK. Overview of the management of osteoporosis in postmenopausal women. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.
12. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019;104(5):1595-1622. doi:10.1210/jc.2019-00221[PubMed 30907953]
13. The Journal of The North American Menopause Society.28(9),973-997
14. J Clin Endocrinol Metab, May 2019,104(5):1595–1622

MedOne P&T Committee approval: Date: 12-1-22

Initial adoption: 5-1-17

Revised: 12-21-22

12-21-22
1. Removed requirement to fail both bisphosphonates and Prolia for high-risk menopausal women
2. Clinical review/studies added to references

8-15-22
1. Pricing updated based off of AWP (8-15-22)

2. Updated fail first criteria from 2 to 1 oral bisphosphonate if treatment failure, 2 if intolerance
3. Added Prolia trial requirement
4. Added max 24 month duration and updated initial duration from 6 to 12 months
5. Added requirement to use as monotherapy

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