Optum Rx®

Criteria for Indiana Medicaid
GLP-1 Receptor Agonists and Combinations

Prepared for State of Indiana by OptumRx

EXECUTIVE SUMMARY

Purpose: Promote prudent prescribing of GLP-1 receptor agonists and combinations

Setting & Population: All members

Type of Criteria:
- ☐ **Increased Risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Non-Preferred Agent**
- ☒ **Other:**

Data Sources:
- ☒ **Only administrative databases**
- ☐ **Databases + Prescriber-supplied**

TARGETED PRODUCTS
DRUG NAME
BYDUREON BCISE (EXENATIDE)
BYETTA (EXENATIDE)
EXENATIDE (generic Byetta)
LIRAGLUTIDE (authorized generic and generic Victoza)
MOUNJARO (TIRZEPATIDE)
OZEMPIC (SEMAGLUTIDE)
RYBELSUS (SEMAGLUTIDE)
SOLIQUA (INSULIN GLARGINE/ LIXISENATIDE)
TRULICITY (DULAGLUTIDE)
VICTOZA (LIRAGLUTIDE)
XULTOPHY (INSULIN DEGLUDEC/ LIRAGLUTIDE)

APPROVAL DURATION

- Initial authorizations will be granted approval for up to 6 months
- Reauthorization will be granted approval for up to 1 year

APPROVAL CRITERIA

Prior authorization for the prescribed drug will be granted when the following approval criteria has been met:

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PREFERRED AGENTS

BYETTA (EXENATIDE) and EXENATIDE (generic Byetta) – IMMEDIATE RELEASE

Initial Authorization

- Must meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
  - One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - One of the following:
    - Previous trial of metformin for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
    - Documented intolerance or contraindication to metformin therapy
  - Dose requested does not exceed 20 mcg/day

Reauthorization

- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
  - Member is not on concomitant DPP-4 inhibitor-containing therapy
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Dose requested does not exceed 20 mcg/day

OZEMPIC (SEMAGLUTIDE)

Initial Authorization

- Must meet all of the following:
  - Member is 18 years of age or older
  - One of the following:
    - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease and/or chronic kidney disease, as confirmed by chart documentation or claims history AND both of the following:
      - One of the following:
        - Previous trial of metformin for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
        - Documented intolerance or contraindication to metformin therapy
      - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product

- Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD) AND all of the following:
  - Diagnosis has been confirmed by one of the following methods (documentation required):
    - FibroScan assessed liver stiffness (FAST) score ≥ 0.67
    - Fibrosis-4 Index (FIB-4) score (must be ≥ 35 years of age) 2.67-3.47
    - Liver biopsy
    - MEFIB score with the following:
      - FIB-4 ≥ 1.6
      - Magnetic resonance elastography (MRE) ≥ 3.3 kPA
    - MRE 3.63 – 5 kPA
    - MRI-PDFF, MRE, and serum AST (MAST) score ≥0.242
  - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist
  - Prescriber attests that member does not have any of the following:
    - Celiac disease
    - Daily alcohol consumption exceeding 30 grams (2 standard drinks) per day
    - Familial hypobetalipoproteinemia (FHBL)
    - Hepatitis A, B, or C
    - Lysosomal acid lipase (LAL) deficiency
    - Wilson disease
  - Member does not have history of any of the following in the past 90 days OR prescriber attests that alternate therapies are not appropriate for the member and prescriber has a monitoring plan in place:
    - Amiodarone
    - Glucocorticoids
    - Methotrexate
    - Synthetic estrogens
    - Tamoxifen
- One of the following:
  - Member is not on concomitant DPP-4 inhibitor-containing agent
  - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
- Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Dose requested does not exceed 2 mg/week

Reauthorization

- Must meet all of the following:
  - One of the following:
    - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease and/or chronic kidney disease, as confirmed by chart documentation or claims history and one of the following:
      - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
      - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
    - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD), as confirmed by chart documentation or claims history
  - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - Member is not on concomitant DPP-4 inhibitor therapy
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Dose requested does not exceed 2 mg/week

TRULICITY (DULAGLUTIDE)

Initial Authorization
- Must meet all of the following:
  - Member is 10 years of age or older
  - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease or cardiovascular disease risk factors, as confirmed by chart documentation or claims history
  - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
  - One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - One of the following:
    - Previous trial of metformin for at least 90 days within that past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
    - Documented intolerance or contraindication to metformin therapy
  - Dose requested does not exceed one of the following:
    - 0.75 mg injection: 2 injections/week
    - 1.5 mg, 3 mg, or 4.5 mg injection: 1 injection/week

Reauthorization
- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease or cardiovascular disease risk factors, as confirmed by chart documentation or claims history
  - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
  - Member is not on concomitant DPP-4 inhibitor-containing therapy
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Dose requested does not exceed one of the following:
    - 0.75 mg injection: 2 injections/week
    - 1.5 mg, 3 mg, or 4.5 mg injection: 1 injection/week

VICTOZA (LIRAGLUTIDE), LIRAGLUTIDE (authorized generic and generic Victoza)

Initial Authorization
- Must meet all of the following:
  - Member is 10 years of age or older
  - One of the following:
    - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease, as confirmed by chart documentation or claims history AND both of the following:
      - One of the following:
        - Previous trial of metformin for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

        - Documented intolerance or contraindication to metformin therapy
    - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
- Diagnosis of polycystic ovary syndrome, as confirmed by chart documentation or claims history AND one of the following:
    - Previous trial of metformin for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
    - Documented intolerance or contraindication to metformin therapy
- Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD) AND all of the following:
    - Diagnosis has been confirmed by one of the following methods (documentation required):
        - FibroScan assessed liver stiffness (FAST) score ≥ 0.67
        - Fibrosis-4 Index (FIB-4) score (must be ≥ 35 years of age) 2.67-3.47
        - Liver biopsy
        - MEFIB score with the following:
            - FIB-4 ≥ 1.6
            - Magnetic resonance elastography (MRE) ≥ 3.3 kPA
        - MRE 3.63 – 5 kPA
        - MRI-PDFF, MRE, and serum AST (MAST) score ≥0.242
    - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist
    - Prescriber attests that member does not have any of the following:
        - Celiac disease
        - Daily alcohol consumption exceeding 30 grams (2 standard drinks) per day
        - Familial hypobetalipoproteinemia (FHBL)
        - Hepatitis A, B, or C
        - Lysosomal acid lipase (LAL) deficiency
        - Wilson disease
    - Member does not have history of any of the following in the past 90 days OR prescriber attests that alternate therapies are not appropriate for the member and prescriber has a monitoring plan in place:
        - Amiodarone
        - Glucocorticoids
        - Methotrexate
        - Synthetic estrogens
        - Tamoxifen
- One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
- Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Dose requested does not exceed 1.8 mg/day

Reauthorization

- Must meet <u>all</u> of the following:
    - One of the following:
        - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease, as confirmed by chart documentation or claims history and <u>one</u> of the following:
            - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)

- Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
- Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD), as confirmed by chart documentation or claims history
- Diagnosis of polycystic ovary syndrome, as confirmed by chart documentation or claims history
- History of Victoza or liraglutide (Victoza generic or authorized generic) for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Member is not on concomitant DPP-4 inhibitor-containing therapy
- Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Dose requested does not exceed 1.8 mg/day

SOLIQUA (INSULIN GLARGINE/LIXISENATIDE)

Initial Authorization
- Must meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
  - One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Previous trial of a preferred non-insulin injectable hypoglycemic or long-acting insulin for at least 90 days in the past 120 days
  - Dose requested does not exceed 60 units insulin glargine/20 mcg lixisenatide per day

Reauthorization
- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
  - Member is not on concomitant DPP-4 inhibitor-containing therapy
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Dose requested does not exceed 60 units insulin glargine/20 mcg lixisenatide per day

NON-PREFERRED AGENTS

BYDUREON BCISE (EXENATIDE) – EXTENDED RELEASE

Initial Authorization
- Must meet all of the following:
  - Member is 10 years of age or older

- Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
- Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
- One of the following:
  - Member is not on concomitant DPP-4 inhibitor-containing agent
  - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
- Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
  - Both of the following:
    - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
    - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
  - Medical justification for use of Bydureon BCise (exenatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
- Dose requested does not exceed 2 mg/week

Reauthorization

- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
    - Both of the following:
      - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
      - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
    - Medical justification for use of Bydureon BCise (exenatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
  - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
  - Member is not on concomitant DPP-4 inhibitor-containing therapy
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Dose requested does not exceed 2 mg/week

MOUNJARO (TIRZEPATIDE)

Initial Authorization
- Must meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
  - One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
    - Both of the following:
      - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
      - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
    - Medical justification for use of Mounjaro (tirzepatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
  - Dose requested does not exceed 15 mg/week

Reauthorization
- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
    - Both of the following:
      - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
      - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
    - Medical justification for use of Mounjaro (tirzepatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
  - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)

        - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
    - Member is not on concomitant DPP-4 inhibitor-containing therapy
    - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
    - Dose requested does not exceed 15 mg/week

RYBELSUS (SEMAGLUTIDE)

Initial Authorization
- Must meet all of the following:
    - Member is 18 years of age or older
    - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
    - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
    - One of the following:
        - Member is not on concomitant DPP-4 inhibitor-containing agent
        - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
    - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
    - Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
        - Both of the following:
            - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
            - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
        - Medical justification for use of Rybelsus (semaglutide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
    - Dose requested does not exceed 1 tablet/day

Reauthorization
- Must meet all of the following:
    - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
    - Previous trial and failure of TWO different preferred GLP-1 RA agents, at least one of the two preferred GLP-1 RA trials must consist of either Ozempic (semaglutide) or Trulicity (dulaglutide) AND one of the following:
        - Both of the following:
            - History of at least 90 days of preferred GLP-1 RA therapy at an optimized dose (Table 1) for each agent, supported by claims history, chart documentation, or provider attestation including dates of trial
            - Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to each of the two preferred agents trialed
        - Medical justification for use of Rybelsus (semaglutide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes, gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)
    - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

- One of the following:
  - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
  - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
- Member is not on concomitant DPP-4 inhibitor-containing therapy
- Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Dose requested does not exceed 1 tablet/day

XULTOPHY (INSULIN DEGLUDEC/LIRAGLUTIDE)

Initial Authorization

- Must meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Prescriber has submitted baseline HbA1c, obtained within the past 90 days (submitted lab documentation required), prior to initiating the requested GLP-1 RA or combination product
  - One of the following:
    - Member is not on concomitant DPP-4 inhibitor-containing agent
    - Member will be transitioning from DPP-4 inhibitor-containing therapy to GLP-1 RA-containing therapy (45-day transition period permitted)
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product
  - Must meet one of the following:
    - Trial and failure of Soliqua (insulin glargine/lixisenatide), as confirmed by claims history, chart documentation, or provider attestation including dates of trial
    - Both of the following:
      - Medical justification for use of Xultophy (insulin degludec/liraglutide) over Soliqua (insulin glargine/lixisenatide)
      - Previous trial of a preferred non-insulin injectable hypoglycemic or long-acting insulin for at least 90 days in the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - Dose requested does not exceed 50 units insulin degludec/1.8 mg liraglutide per day

Reauthorization

- Must meet all of the following:
  - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history
  - Must meet one of the following:
    - Prior history of Soliqua (insulin glargine/lixisenatide), as confirmed by claims history, chart documentation, or provider attestation including dates of trial
    - Medical justification for use of Xultophy (insulin degludec/liraglutide) over) over Soliqua (insulin glargine/lixisenatide)
  - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
  - One of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, demonstrating a reduction in HbA1c from the baseline value obtained prior to initiating the requested agent (must submit documentation of baseline HbA1c or provide value of baseline HbA1c, including date and time of collection)
    - Prescriber has submitted HbA1c lab documentation, obtained within the past 90 days, and has submitted medical justification for continued use, supported by documentation within submitted chart notes
  - Member is not on concomitant DPP-4 inhibitor-containing therapy

- Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product
- Dose requested does not exceed 50 units insulin degludec/1.8 mg liraglutide per day

Table 1: Optimized Dose

AGENT	OPTIMIZED DOSE
Byetta (exenatide)	10 mcg twice daily
Ozempic (semaglutide)	2 mg weekly
Trulicity (dulaglutide)	4.5 mg weekly
Victoza (liraglutide)	1.8 mg daily

☐ Existing Criteria
☒ Revision of Existing Criteria
☐ New Criteria