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
EXENATIDE
LIRAGLUTIDE (authorized generic and generic Victoza)
MOUNJARO (TIRZEPATIDE)
OZEMPIC (SEMAGLUTIDE)
RYBELSUS (SEMAGLUTIDE)
SOLIQUA (INSULIN GLARGINE/ LIXISENATIDE)
TRULICITY (DULAGLUTIDE)
WEGOVY (SEMAGLUTIDE)
VICTOZA (LIRAGLUTIDE)
XULTOPHY (INSULIN DEGLUDEC/ LIRAGLUTIDE)
ZEPBOUND (TIRZEPATIDE)

APPROVAL DURATION

- Initial authorizations will be granted approval for up to 6 months, unless otherwise specified in criteria below
- 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:

PREFERRED AGENTS

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 (1-year approval):
      - Diagnosis has been confirmed by one of the following methods (documentation required):
        - Liver biopsy obtained within the past 2 years illustrating the following scores:
          - MASH indication: non-alcoholic fatty liver disease activity score (NAS) of ≥ 4 with a score of at least 1 in each of the following NAS components: steatosis, ballooning degeneration, and lobular inflammation AND METAVIR stage of F1-F3 fibrosis
          - MASLD indication: score of at least 1 in steatosis category
        - Vibration-controlled transient elastography (e.g., Fibroscan) obtained within the past 6 months illustrating the following scores:
          - MASH indication: results with a liver stiffness measurement (LSM) ≥ 6.43 kPa and controlled attenuation parameter (CAP) ≥ 238 dB/m
          - MASLD indication: controlled attenuation parameter (CAP) ≥ 238 dB/m
      - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist
  - 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 both of the following:
      - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
        - Members who have been on requested therapy for <1 year: within the past 90 days
        - Members who have been on requested therapy for ≥1 year: within the past 180 days
      - One of the following:
        - Submitted HbA1c demonstrates 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)
- Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
- Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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 and the following:
  - Prescriber must provide documentation of current clinical status, including one of the following:
    - Liver biopsy results within the past year demonstrating improvement or stabilization in fibrosis staging and NAS score from baseline
    - Fibroscan results within the past year demonstrating improvement or stabilization in CAP and LSM scores

- 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

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
  - Both of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
      - Members who have been on requested therapy for <1 year: within the past 90 days
      - Members who have been on requested therapy for ≥1 year: within the past 180 days
    - One of the following:

- Submitted HbA1c demonstrates 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)
- Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
- Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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

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
  - Both of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
      - Members who have been on requested therapy for <1 year: within the past 90 days
      - Members who have been on requested therapy for ≥1 year: within the past 180 days
    - One of the following:
      - Submitted HbA1c demonstrates 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)
      - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year

- Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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 (1-year approval):
      - Diagnosis has been confirmed by one of the following methods (documentation required):
        - Liver biopsy obtained within the past 2 years illustrating the following scores:
          - MASH indication: non-alcoholic fatty liver disease activity score (NAS) of ≥ 4 with a score of at least 1 in each of the following NAS components: steatosis, ballooning degeneration, and lobular inflammation AND METAVIR stage of F1-F3 fibrosis
          - MASLD indication: score of at least 1 in steatosis category
        - Vibration-controlled transient elastography (e.g., Fibroscan) obtained within the past 6 months illustrating the following scores:
          - MASH indication: results with a liver stiffness measurement (LSM) ≥ 6.43 kPa and controlled attenuation parameter (CAP) ≥ 238 dB/m
          - MASLD indication: controlled attenuation parameter (CAP) ≥ 238 dB/m
      - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist
  - 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 all 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 both of the following:
      - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
        - Members who have been on requested therapy for <1 year: within the past 90 days
        - Members who have been on requested therapy for ≥1 year: within the past 180 days
      - One of the following:
        - Submitted HbA1c demonstrates 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)
        - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
        - Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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 and the following:
      - Prescriber must provide documentation of current clinical status, including one of the following:
        - Liver biopsy results within the past year demonstrating improvement or stabilization in fibrosis staging and NAS score from baseline
        - Fibroscan results within the past year demonstrating improvement or stabilization in CAP and LSM scores
    - 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

ZEPBOUND (TIRZEPATIDE) (NOT COVERED EXCLUSIVELY FOR WEIGHT LOSS)

Initial Authorization (1-year approval)
- Must meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of moderate to severe obstructive sleep apnea (OSA) (i.e., apnea hypopnea index (AHI) of ≥ 15 events/hour) in individuals with obesity AND all of the following:
    - Member has a documented BMI of ≥ 30 kg/m^2 before initiating Zepbound (supported by chart documentation, including baseline weight before initiating Zepbound, obtained within the past 3 months)
    - One of the following:
      - Member has an AHI of ≥ 15 events/hour (i.e., indicating moderate to severe OSA), as measured on polysomnography (PSG) or home sleep apnea test (HSAT) that has been

reviewed and interpreted by a sleep medicine-certified physician (supported by documentation from a PSG or HSAT obtained within the past year) -OR-
- Member has had a prior apnea hypopnea index (AHI) of ≥ 15 events/hour, as measured on polysomnography (PSG) or home sleep apnea test (HSAT) that was reviewed and interpreted by a sleep medicine-certified physician (supported by documentation) AND prescriber has submitted documentation confirming member has been utilizing positive airway pressure (PAP) therapy (e.g., CPAP, BiPAP) with documented adherence from within the past 90 days (adherence defined as ≥ 4 hours of use per night for ≥ 70 percent of all nights within a 30-day period, supported by submitted PAP therapy report or chart note documentation) OR prescriber has provided valid medical justification as to why the member cannot utilize PAP therapy (e.g., individuals living with intellectual disabilities)
    - Member does not have Type 1 or Type 2 diabetes mellitus
    - Member's HbA1c is less than 6.5% (supported by chart documentation from within the past 3 months)
  - Prescriber attests to all of the following:
    - Member does not have diagnosis of central or mixed sleep apnea with percent of mixed or central apneas/hypopneas ≥ 50%
    - Member will use Zepbound (tirzepatide) in combination with reduced calorie diet and increased physical activity
  - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product (including tirzepatide-containing products)
  - Dose requested does not exceed 15 mg/week

Reauthorization
- Must meet all of the following:
  - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history or chart documentation
  - On initial reauthorization ONLY (members who have been on requested therapy for > 1 year and < 2 years), member demonstrates a documented reduction in AHI from baseline study (e.g., PSG or HSAT that was reviewed and interpreted by a sleep medicine-certified physician, CPAP or BiPAP sleep data) obtained within the past 3 months
  - Member demonstrates a meaningful weight loss from baseline (defined as a weight loss of at least 5% from baseline)
  - Prescriber attests to all of the following:
    - Member does not have Type 1 or Type 2 diabetes mellitus
    - Member has not been diagnosed with central or mixed sleep apnea
  - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product (including tirzepatide-containing products)
  - Dose requested does not exceed 15 mg/week

NON-PREFERRED AGENTS

EXENATIDE – 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

- 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 exenatide over 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 20 mcg/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 exenatide over 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
  - Both of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
      - Members who have been on requested therapy for <1 year: within the past 90 days
      - Members who have been on requested therapy for ≥1 year: within the past 180 days
    - One of the following:
      - Submitted HbA1c demonstrates 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)
      - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
      - Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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

MOUNJARO (TIRZEPATIDE)

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) – as applicable based on FDA approved age limit – 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 Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) – as applicable based on FDA approved age limit (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)
  - One of the following:
    - Member is 18 years of age or older: dose requested does not exceed 15 mg/week
    - Member is less than 18 years of age: dose requested does not exceed 10 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) – as applicable based on FDA approved age limit – 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 Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) – as applicable based on FDA approved age limit (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
  - Both of the following:
    - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
      - Members who have been on requested therapy for <1 year: within the past 90 days
      - Members who have been on requested therapy for ≥1 year: within the past 180 days

        - One of the following:
            - Submitted HbA1c demonstrates 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)
            - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
            - Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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
    - One of the following:
        - Member is 18 years of age or older: dose requested does not exceed 15 mg/week
        - Member is less than 18 years of age: dose requested does not exceed 10 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 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 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
- Both of the following:
  - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
    - Members who have been on requested therapy for <1 year: within the past 90 days
    - Members who have been on requested therapy for ≥1 year: within the past 180 days
  - One of the following:
    - Submitted HbA1c demonstrates 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)
    - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
    - Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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

WEGOVY (SEMAGLUTIDE) INJECTION FORMULATION (NOT COVERED EXCLUSIVELY FOR WEIGHT LOSS)

Initial Authorization (1-year approval)

- Must meet all of the following:
  - One of the following:
    - Diagnosis of cardiovascular disease (CVD) in obese or overweight individuals who need risk reduction of major adverse cardiovascular events (MACE) AND all of the following:
      - Member is 45 years of age or older
      - Member has a BMI of ≥ 27 kg/m2 (supported by chart documentation from within the past 3 months)
      - Member has one of the following: (supported by chart documentation from within the past year)
        - Prior myocardial infarction (MI)
        - Prior stroke (ischemic or hemorrhagic)
        - Symptomatic peripheral arterial disease (PAD) as evidenced by one of the following:
          - Amputation due to atherosclerotic disease
          - History of peripheral arterial revascularization procedure
          - Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)
      - One of the following:

        - Member is optimized on guideline-directed therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents (supported by chart documentation or claims history)
        - Prescriber has provided medical justification as to why member cannot use beta-blockers, RAS inhibitors, AND lipid-lowering therapies (provider must include dates of trial, if applicable)
    - Prescriber attests to all of the following:
        - Member does not have Type 1 or Type 2 diabetes
        - Member will use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
        - Member will not use with other semaglutide products or with any other GLP-1 RA or combination products
- Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) AND all of the following:
    - Member is 18 years of age or older
    - Diagnosis has been confirmed by one of the following methods (documentation required):
        - Liver biopsy obtained within the past 2 years illustrating the following scores:
            - Non-alcoholic fatty liver disease activity score (NAS) of ≥ 4 with a score of at least 1 in each of the following NAS components: steatosis, ballooning degeneration, and lobular inflammation
            - METAVIR stage of F2-F3 fibrosis and no evidence of cirrhosis
        - Vibration-controlled transient elastography (e.g., Fibroscan) obtained within the past 6 months illustrating the following scores:
            - Results with a liver stiffness measurement (LSM) ≥ 9.1 kPa
            - Controlled attenuation parameter (CAP) ≥ 280 dB/m
    - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist
    - One of the following:
        - Member will not be using Wegovy (semaglutide) concurrently with Rezdiffra (resmetirom)
        - Prescriber has provided valid medical justification for the concurrent use of Wegovy (semaglutide) and Rezdiffra (resmetirom)
    - One of the following:
        - Member does not have Type 2 diabetes (T2D)
        - Member has concomitant T2D with MASH and has utilized Ozempic at 2 mg/week consistently for at least 18 months (confirmed by claims history or chart documentation) AND has demonstrated inadequate reduction in fibrosis and/or steatosis, confirmed by liver biopsy and/or non-invasive tests (baseline reports must be submitted along with testing documentation collected within the past 6 months)
    - Member will not be utilizing the requested agent concurrently with another GLP-1 RA or combination product (including semaglutide-containing products)
    - Prescriber attests to the following:
        - Member will use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
- Dose requested does not exceed 2.4 mg/week

Reauthorization

- Must meet all of the following:
    - History of requested agent for at least 84 days within the past 112 days, as confirmed by claims history or chart documentation
    - One of the following:
        - Diagnosis of cardiovascular disease (CVD) in obese or overweight individuals who need risk reduction of major adverse cardiovascular events (MACE) AND all of the following:
            - Prescriber attests to all of the following:
                - Member does not have Type 1 or Type 2 diabetes

        - Member will continue to use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
        - Member will not use with other semaglutide products or with any other GLP-1 RA or combination agents
    - One of the following:
        - Member continues to utilize guideline-directed therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents (supported by chart documentation or claims history)
        - Prescriber has provided medical justification as to why member cannot use beta-blockers, RAS inhibitors, AND lipid-lowering therapies (provider must include dates of trial, if applicable)
- Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) AND all of the following:
    - Prescriber must provide documentation of current clinical status, including one of the following:
        - Liver biopsy results within the past year demonstrating improvement or stabilization in fibrosis staging and NAS score from baseline
        - Fibroscan results within the past year demonstrating improvement or stabilization in CAP and LSM scores
    - Member is not utilizing the requested agent concurrently with another GLP-1 RA or combination product (including semaglutide-containing products)
    - Prescriber attests to the following:
        - Member will continue to use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
- Dose requested does not exceed 2.4 mg/week

WEGOVY (SEMAGLUTIDE) ORAL FORMULATION (NOT COVERED EXCLUSIVELY FOR WEIGHT LOSS)

Initial Authorization (1-year approval)

- Must meet all of the following:
    - Diagnosis of cardiovascular disease (CVD) in obese or overweight individuals who need risk reduction of major adverse cardiovascular events (MACE) AND all of the following:
        - Member is 45 years of age or older
        - Member has a BMI of ≥ 27 kg/m2 (supported by chart documentation from within the past 3 months)
        - Member has one of the following: (supported by chart documentation from within the past year)
            - Prior myocardial infarction (MI)
            - Prior stroke (ischemic or hemorrhagic)
            - Symptomatic peripheral arterial disease (PAD) as evidenced by one of the following:
                - Amputation due to atherosclerotic disease
                - History of peripheral arterial revascularization procedure
                - Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)
        - One of the following:
            - Member is optimized on guideline-directed therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents (supported by chart documentation or claims history)
            - Prescriber has provided medical justification as to why member cannot use beta-blockers, RAS inhibitors, AND lipid-lowering therapies (provider must include dates of trial, if applicable)
        - Prescriber attests to all of the following:
            - Member does not have Type 1 or Type 2 diabetes
            - Member will use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
            - Member will not use with other semaglutide products or with any other GLP-1 RA or combination products

- Prescriber has submitted medical justification for the use of Wegovy oral formulation over Wegovy subcutaneous injection (supported by chart documentation)
- Dose requested does not exceed 25 mg/day AND the following:
  - 1.5 mg tablet – max 1 tablet/day
  - 4 mg tablet – max 1 tablet/day
  - 9 mg tablet – max 1 tablet/day
  - 25 mg tablet – max 1 tablet/day

Reauthorization

- Must meet all of the following:
  - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history or chart documentation
  - Diagnosis of cardiovascular disease (CVD) in obese or overweight individuals who need risk reduction of major adverse cardiovascular events (MACE) AND all of the following:
    - Prescriber attests to all of the following:
      - Member does not have Type 1 or Type 2 diabetes
      - Member will continue to use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
      - Member will not use with other semaglutide products or with any other GLP-1 RA or combination agents
    - One of the following:
      - Member continues to utilize guideline-directed therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents (supported by chart documentation or claims history)
      - Prescriber has provided medical justification as to why member cannot use beta-blockers, RAS inhibitors, AND lipid-lowering therapies (provider must include dates of trial, if applicable)
  - Prescriber has submitted medical justification for the use of Wegovy oral formulation over Wegovy subcutaneous injection (supported by chart documentation)
  - Dose requested does not exceed 25 mg/day AND the following:
    - 1.5 mg tablet – max 1 tablet/day
    - 4 mg tablet – max 1 tablet/day
    - 9 mg tablet – max 1 tablet/day
    - 25 mg tablet – max 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 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
    - Both of the following:
        - Prescriber has submitted HbA1c lab documentation, obtained within one of the following timeframes:
            - Members who have been on requested therapy for <1 year: within the past 90 days
            - Members who have been on requested therapy for ≥1 year: within the past 180 days
        - One of the following:
            - Submitted HbA1c demonstrates 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)
            - Submitted HbA1c demonstrates a reduction or trend towards stabilization over the past year
            - Submitted HbA1c does NOT demonstrate 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) OR does NOT demonstrate a reduction or trend towards stabilization in HbA1c over the past year AND prescriber 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
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