Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist

1. Does the member have a diagnosis of Type 2 Diabetes Mellitus?
   a. Yes- Move to question 2
   b. No- Deny- Category 3- *Not a covered benefit GLP-1 receptor agonists are FDA approved as a treatment of type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise. OHP only pays for treatment as approved by the FDA.*

2. Is the member newly diagnosed?
   a. Yes – Deny Cat 5- *Not medically appropriate*. *An appropriate period of lifestyle modification and traditional anti- diabetic medication (metformin, pioglitazone, a sulfonylurea or basal insulin) are required before consideration of GLP-1 therapy.*
   b. No – Move to question 3

3. Has the member tried and failed triple therapy of preferred agents? Must have used 2 or more antidiabetic agents concurrently for at least 6 months without achieving glycemic control, must also demonstrate that therapy has been adjusted in an effort to achieve glycemic control. (i.e. sulfonylurea changed to pioglitazone, insulin added to regimen, etc.)

   Preferred agents: Metformin, sulfonylurea, pioglitazone, basal insulin, DPP-4 inhibitors, acarbose. *If not using metformin due to side effects, must have documentation that member was titrated correctly, in an effort to reduce side effects OR retrial of medication. See below*

   a. Yes – Move to question 4
   b. No- Deny Category 5- *Not medically appropriate- Provider submitted documentation does not indicate that member has tried and failed, or has a contraindication to, preferred treatment options.*

4. Does member demonstrate compliance to current diabetic therapy?
   (Must show 80% or better adherence)
   a. Yes- Move to question 5
   b. No – Deny- Cat 5- *Not medically appropriate- Escalation of therapy is not appropriate if member is not compliant with current treatment.*

5. Is the request for a formulary GLP-1 agent? Exenatide (Bydureon) Dulaglutide (Trulicity) or Liraglutide (Victoza)
   a. Yes – Move to question 7
   b. No- Move to question 6

6. Has the member tried and failed formulary GLP-1 agents?
   a. Yes – Move to question 7
   b. No – Deny Cat 15 – *Not a covered benefit- Provider submitted documentation does not indicate that member has tried and failed formulary alternatives, Bydureon, Trulicity or Victoza.*
7. Is the dosing within FDA approved parameters for the requested medication?
   (All SubQ injection)
   - Exenatide (Bydureon) 2 mg once weekly
   - Exenatide (Byetta) 5 to 10 mcg twice daily
   - Liraglutide (Victoza) 0.6 to 1.8 mg once daily
   - Albiglutide (Tanzeum): 30 to 50 mg once weekly
   - Dulaglutide (Trulicity) 0.75 to 1.5 mg once weekly
   - Lixisenatide (Adlyxin) 10 to 20 mcg once daily

a. Yes- Approve for 6 month trial
b. No- Cat 3- not a covered benefit –*The requested dosing is outside FDA approved dosing, safety and efficacy have not been established.*

Renewal Criteria

1. Has the member been compliant with GLP-1 AND all other anti-diabetic therapy?
   a. Yes- Move to question 2
   b. No – Approve for another 6 month trial- Continued authorization will require that member demonstrate adherence to anti- diabetic therapy.

2. Has member shown improvement in glycemic control (Lowered HbA1c)?
   a. Yes- Approve for up to 1 year
   b. No- *Approve for another 6 month trial (if appropriate) OR forward to medical director for evaluation of medication efficacy.*

Dipeptidyl Peptidase-4 Inhibitor (DPP-4) PA criteria

1. Does the member have a diagnosis of Type 2 Diabetes Mellitus (T2DM)
   a. Yes- Move to question 2
   b. No- Deny Cat 3- *not a covered benefit –DPP-4 inhibitors are only indicated for the treatment of T2DM*

2. Is the member newly diagnosed?
   a. Yes – Deny Cat 5- *Not medically appropriate*. *An appropriate period of lifestyle modification and traditional anti- diabetic medication (metformin, pioglitazone, a sulfonylurea or basal insulin) are required before consideration of DPP-4 therapy.*
   b. No – Move to question 3

3. Has the member tried and failed combination therapy of preferred agents? Must have used 2 or more antidiabetic agents concurrently for at least 6 months without achieving glycemic control. Must demonstrate that therapy was adjusted in an attempt to achieve glycemic control.
   Preferred agents include- Metformin, a sulfonylurea, acarbose and pioglitazone
   If not using metformin due to side effects, must have documentation that member was titrated correctly in an effort to reduce side effects OR retrial of medication. See below
   a. Yes- Move to question 4
   b. No- Denied Cat 5 – *Not Medically Appropriate*. *Provider submitted documentation does not indicate that member has tried and failed, or has a contraindication to, preferred treatment options.*

4. Has member shown to compliance with current diabetic therapy? (80% or better adherence)
   a. Yes- Move to question 5
   b. No- Deny Cat 5 - *Not medically appropriate- Escalation of therapy is not appropriate if member is not compliant with current treatment*

5. Is the request for formulary DPP-4 inhibitors alogliptin (Nesina- generic available) or sitagliptin (Januvia)?
   a. Yes- Move to question 7
   b. No – Move to question 6

6. Has the member tried and failed formulary options of alogliptin (Nesina), linagliptin (Tradjenta) and sitagliptin(Januvia)?
   a. Yes- Move to question 7
   b. No- Deny Cat 15 - *Not a covered benefit- Provider submitted documentation does not indicate that member has tried and failed formulary alternatives of alogliptin, linagliptin and sitagliptin.*

7. Is the medication dosing within FDA approved dosing parameters for the medication?

   - Alogliptin (Nesina): 25mg once daily
   - Sitagliptin : 100 mg once daily
   - Linagliptin: 5 mg once daily
   - Saxagliptin: 2.5 to 5 mg once daily

   a. Yes – Approve for up to 1 year
   b. No – *Deny Cat 3 – Not a covered benefit. The requested medication dosing is outside of the FDA approved dosing, safety and efficacy cannot be established at the requested dose.*

Sodium-Glucose Co-Transporter 2 Inhibitors (SGLT2) PA criteria

1. Does the member have a diagnosis of Type 2 Diabetes Mellitus (T2DM)
   a. Yes- Move to question 2
   b. No- Deny Cat 3- *not a covered benefit –SGLT2 inhibitors are only indicated for the treatment of T2DM*

2. Is the member newly diagnosed?
   a. Yes – Deny Cat 5- *Not medically appropriate. An appropriate period of lifestyle modification and traditional anti- diabetic medication (metformin, pioglitazone, a sulfonylurea or basal insulin) are required before consideration of DPP-4 therapy.*
   b. No – Move to question 3

3. Does the member have a history of severe renal impairment (eGFR < 30 ml/min), ESRD or is member on dialysis?

   a. Yes –Cat 5 *Not Medically Appropriate – This conditions represent contraindications to therapy with SGLT2 inhibitors.*
   b. No- Move to question 4

4. Has the member tried and failed or have contraindication with combination therapy with 3 preferred treatment agents? Must have used 3 or more antidiabetic agents concurrently for at least 6 months without achieving glycemic control. Must demonstrate that therapy was adjusted in an attempt to achieve glycemic control.

Preferred treatments are metformin, a sulfonylurea, pioglitazone, DPP-4 inhibitor, GLP-1 agonist and basal insulin.

   a. Yes- Move to question 5
   b. No- Denied Cat 5 – *Not Medically Appropriate. Provider submitted documentation does not indicate that member has tried and failed, or has a contraindication to, preferred treatment options*

5. Has member shown to compliance with current diabetic therapy? (80% or better adherence)
   a. Yes- Move to question 6
   b. No- Deny Cat 5 - *Not medically appropriate- Escalation of therapy is not appropriate if member is not compliant with current treatment*

6. Is the request for a formulary SGLT2 inhibitor? Empagliflozin (Jardiance) is formulary.
   a. Yes- Move to question 8
   b. No- Move to question 7

7. Has the member tried and failed formulary empagliflozin (Jardiance)?
   a. Yes- Move to question 8
   b. No- Deny Cat 15- *Not a covered benefit- Provider submitted documentation does not indicate that member has tried and failed formulary option of empagliflozin*.

8. Is the dosing within the FDA approved parameters for this medication?
   - Empagliflozin (Jardiance) – 10 to 25 mg once daily
   - Canagliflozin (Invokana) – 100 to 300 mg once daily
   - Dapagliflozin (Farxiga) – 5 to 10 mg once daily

   a. Yes- Approve for up to one year
   b. No- *Deny Cat 3 Not a covered benefit. The requested medication is outside FDA approved dosing, safety and efficacy have not been established at this dose*.

Metformin Titration:

Begin with 500 mg tablet once daily with evening meal. If immediately tolerated, may add a second 500 mg dose with breakfast (IR) or at evening meal (XR)

Dose should be increased slowly, add one tablet every 2 to 3 weeks as necessary. If gastrointestinal side effects appear as doses advance, decrease to previous lower dose and try to advance the dose at a later time.

The maximum effective dose can be up to 1,000 mg twice per day but is often 850 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day.

Extended release metformin is associated with fewer side effects and is a preferred form. The entire dose can be given at dinner time with extended release tablets.