STEP THERAPY CRITERIA

CATEGORY **ANTIDIABETIC AGENTS**

DRUG CLASS
BRAND NAME
(generic)

AMYLIN ANALOG:

SYMLINPEN
(pramlintide acetate)

GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONIST:

ADLYXIN
(lixisenatide)

BYDUREON
(exenatide extended-release)

BYDUREON BCISE
(exenatide extended-release)

BYETTA
(exenatide)

OZEMPIC
(semaglutide)

RYBELSUS
(semaglutide)

TANZEUM
(albiglutide)

TRULICITY
(dulaglutide)

VICTOZA
(liraglutide)

SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR:

FARXIGA
(dapagliflozin)

INVOKANA

(canagliflozin)

JARDIANCE
(empagliflozin)

STEGLATRO
(ertugliflozin)

SGLT2 INHIBITOR / METFORMIN:

INVOKAMET
(canagliflozin / metformin HCl)

INVOKAMET XR
(canagliflozin /metformin HCl extended-release)

SEGLUROMET
(ertugliflozin / metformin HCl)

SYNJARDY
(empagliflozin / metformin HCl)

SYNJARDY XR
(empagliflozin / metformin HCl extended-release)

XIGDUO XR
(dapagliflozin / metformin HCl)

SGLT2 INHIBITOR / DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITOR:

GLYXAMBI
(empagliflozin / linagliptin)

QTERN
(dapagliflozin / saxagliptin)

STEGLUJAN
(ertugliflozin / sitagliptin)

SGLT2 INHIBITOR / DPP4 INHIBITOR / METFORMIN:

QTERNMET XR
(dapagliflozin / saxagliptin / metformin HCl extended-release)

TRIJARDY XR
(empagliflozin / linagliptin / metformin HCl extended-release)

LONG ACTING INSULIN/GLP-1 RECEPTOR AGONIST:
SOLIQUA
(insulin glargine / lixisenatide injection)

XULTOPHY
(insulin degludec / liraglutide injection)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA APPROVED INDICATIONS
AMYLIN ANALOG:
SymlinPen
SymlinPen is indicated as an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

GLP-1 RECEPTOR AGONIST:
Adlyxin
Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Adlyxin is not a substitute for insulin. Adlyxin is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- The concurrent use of Adlyxin with short acting insulin has not been studied and is not recommended.
- Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.

Bydureon/Bydureon BCise
Bydureon and Bydureon BCise are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Bydureon/Bydureon BCise are not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
- Bydureon/Bydureon BCise are not a substitute for insulin. Bydureon/Bydureon BCise should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- The concurrent use of Bydureon/Bydureon BCise with insulin has not been studied.
- Bydureon/Bydureon BCise are extended-release formulations of exenatide. Bydureon/Bydureon BCise should not be used with other products containing the active ingredient exenatide.
- Bydureon/Bydureon BCise have not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Byetta
Byetta (exenatide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use

- Byetta is not a substitute for insulin. Byetta should not be used for the treatment of type 1 diabetes or diabetic ketoacidosis, as it would not be effective in these settings.
- The concurrent use of Byetta with prandial insulin has not been studied and cannot be recommended.
- Based on postmarketing data Byetta has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Byetta has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using Byetta. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.

Ozempic

Ozempic is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Limitations of Use

- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic is not a substitute for insulin. Ozempic is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

Rybelsus

Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Rybelsus is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans
- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

Tanzeum

Tanzeum is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Tanzeum is not recommended as first-line therapy for patients inadequately controlled on diet and exercise because of the uncertain relevance of the rodent C-cell tumor findings to humans. Prescribe Tanzeum only to patients for whom the potential benefits are considered to outweigh the potential risk.
- Tanzeum has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Tanzeum is not indicated in the treatment of patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis. Tanzeum is not a substitute for insulin in these patients.
- Tanzeum has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of Tanzeum is not recommended in patients with pre-existing severe gastrointestinal disease.
- Tanzeum has not been studied in combination with prandial insulin.

Trulicity

Trulicity is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use

- Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Trulicity should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Trulicity is not a substitute for insulin.
- Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of Trulicity is not recommended in patients with pre-existing severe gastrointestinal disease.

Victoza
Victoza is indicated:
- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Limitations of Use
- Victoza should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- The concurrent use of Victoza and prandial insulin has not been studied.

SGLT2 INHIBITOR:
Farxiga
Type 2 Diabetes Mellitus
Farxiga (dapagliflozin) is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

Heart Failure
Farxiga is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
Limitation of Use
Farxiga is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Invokana
Invokana (canagliflozin) is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD).
- to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria > 300 mg/day.

Limitations of Use
Invokana is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Jardiance
Jardiance is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus,
- to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease

Limitation of Use
Jardiance is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
Steglatro
Steglatro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
Steglatro is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SGLT2 INHIBITOR / METFORMIN:
Invokamet, Invokamet XR
Invokamet and Invokamet XR are a combination of canagliflozin and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin HCl is appropriate.
Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). However, the effectiveness of Invokamet/Invokamet XR on reducing major cardiovascular events in adults with type 2 diabetes and cardiovascular disease has not been established.

Limitations of Use
Not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Segluromet
Segluromet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.
Limitations of Use
Segluromet is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Synjardy, Synjardy XR
Synjardy and Synjardy XR are a combination of empagliflozin and metformin hydrochloride indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Synjardy/Synjardy XR on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.
Limitation of Use
Synjardy/Synjardy XR is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
Xigduo XR
Xigduo XR (dapagliflozin and metformin HCl extended-release) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.
Limitation of Use
Xigduo XR is not recommended for patients with type 1 diabetes mellitus or diabetic ketoacidosis.

SGLT2 INHIBITOR / DPP-4 INHIBITOR:
Glyxambi
Glyxambi is a combination of empagliflozin and linagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Glyxambi on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.
Limitations of Use
- Glyxambi is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Glyxambi has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi.

Qtern
Qtern (dapagliflozin and saxagliptin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
Qtern is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
Steglujan
Steglujan is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.
Limitations of Use
Steglujan is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Steglujan has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

SGLT2 INHIBITOR / DPP-4 INHIBITOR / METFORMIN:
Qternmet XR
Qternmet XR (dapagliflozin, saxagliptin, and metformin hydrochloride) extended-release tablets is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
Qternmet XR is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
Qternmet XR initiation is intended only for patients currently taking metformin.

Trijardy XR
Trijardy XR is a combination of empagliflozin, linagliptin, and metformin hydrochloride (HCl) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
Trijardy XR is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
Trijardy XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy XR.

LONG ACTING INSULIN / GLP-1 RECEPTOR AGONIST:
Soliqua
Soliqua 100/33 is a combination of insulin glargine and lixisenatide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use:
- Soliqua 100/33 has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis
- Soliqua 100/33 is not recommended for use in combination with any other product containing a
- GLP-1 receptor agonist
- Soliqua 100/33 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis
- Soliqua 100/33 has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis
- Soliqua 100/33 has not been studied in combination with prandial insulin

Xultophy
Xultophy 100/3.6 is a combination of insulin degludec and liraglutide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use:
- Xultophy 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rodent C-cell tumor findings to humans
- Xultophy 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist
- Xultophy 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis
- Xultophy 100/3.6 has not been studied in combination with prandial insulin

INITIAL STEP THERAPY*
**Include Rx and OTC products unless otherwise stated.*

INITIAL STEP THERAPY For AMYLIN ANALOGS (SymlinPen):
If the patient has filled a prescription for at least a 30 day supply of a rapid-acting insulin or short-acting insulin or pre-mixed insulin [e.g., insulin aspart (Novolog), insulin glulisine (Apidra), insulin lispro (Humalog), insulin regular R (Afrezza, Humulin R, Novolin R)] within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the system will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

INITIAL STEP THERAPY For GLP-1 RECEPTOR AGONISTS, SGLT2 INHIBITORS, COMBINATIONS:
If the patient has filled a prescription for at least a 30 day supply of metformin within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria, then the system will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has been receiving the requested drug for at least 3 months **AND**
    - The patient has demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy
      OR
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide), Trulicity (dulaglutide), or Victoza (liraglutide) AND the patient has established cardiovascular disease
      OR
    - The request is for Invokana (canagliflozin) AND the patient has diabetic nephropathy with albuminuria greater than 300 mg per day
      OR
    - The request is for Trulicity (dulaglutide) AND the patient has multiple cardiovascular risk factors
      OR
    - The request is for Farxiga (dapagliflozin) AND the patient has multiple cardiovascular risk factors, or heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

OR

- The request is for SymlinPen (pramlintide acetate) **AND**
    - The patient has a diagnosis of diabetes mellitus AND has failed to achieve desired glucose control despite receiving optimal insulin therapy, including mealtime insulin

OR

- The patient has a diagnosis of type 2 diabetes mellitus **AND**
    - The patient experienced an inadequate treatment response, intolerance, or contraindication to metformin
      OR
    - The patient requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater
      OR
    - The request is for Farxiga (dapagliflozin), Invokana (canagliflozin), Jardiance (empagliflozin), Ozempic (semaglutide), Trulicity (dulaglutide), or Victoza (liraglutide) AND the patient has established cardiovascular disease
      OR
    - The request is for Invokana (canagliflozin) AND the patient has diabetic nephropathy with albuminuria greater than 300 mg per day
      OR
    - The request is for Trulicity (dulaglutide) AND the patient has multiple cardiovascular risk factors
      OR
    - The request is for Farxiga (dapagliflozin) AND the patient has multiple cardiovascular risk factors, or heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

OR

- The request is for Farxiga (dapagliflozin) for a patient with heart failure (New York Heart Association [NYHA] class II-IV) with a reduced ejection fraction of 40 percent or less

REFERENCES

1. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; January 2019.
2. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2019.
3. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019.

4. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2018.
5. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.
6. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2018.
7. Invokamet, Invokamet XR [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2018.
8. Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2019.
9. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2018.
10. Ozempic [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; January 2020.
11. Qtern [package insert]. Wilmington, Delaware: AstraZeneca Pharmaceuticals LP; June 2019.
12. Qternmet XR [package insert]. Wilmington, Delaware: AstraZeneca Pharmaceuticals LP; May 2019.
13. Segluromet [package insert]. Whitehouse Station, NJ: Merck Sharpe & Dohme Corp.; October 2018.
14. Soliqua [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; February 2019.
15. Steglatro [package insert]. Whitehouse Station, NJ: Merck Sharpe & Dohme Corp.; October 2018.
16. Steglujan [package insert]. Whitehouse Station, NJ: Merck Sharpe & Dohme Corp.; October 2018.
17. Symlin/SymlinPen [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2016.
18. Synjardy [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2018.
19. Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2018.
20. Tanzeum [package insert]. Wilmington, DE: GlaxoSmithKline LLC; December 2017.
21. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2020.
22. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2019.
23. Xigduo XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2019.
24. Xultophy [package insert]. Plainsboro, NJ: Novo Nordisk U.S. LLC; February 2019.
25. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed July 2019.
26. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed July 2019.
27. American Diabetes Association. Standards of Medical Care in Diabetes-2019: *Diabetes Care* January 2019;42(Supplement1).
28. Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm 2019, Endocr Pract. 2019; 25(No 1); 69-100.
29. Rybelsus [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; September 2019.
30. Perkovic V, Jardine MJ, Neal B, et al. Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. *N Engl J Med* 2019; 380:2295-306.
31. Trijardy XR [package Insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2020.
32. McMurray JJ, Solomon SD, Inzucchi SE, et al. for the DAPA-HF Trial Committees and Investigators. Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med* 2019; 381;1995-2008.
33. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Am Coll Cardiol*. 2017;70:776–803.

