MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Diabetes	**P&T DATE:**	05/14/2019
CLASS:	Endocrine Disorders	**REVIEW HISTORY** (MONTH/YEAR)	11/06, 09/07, 02/08, 11/09, 02/11, 05/12, 09/14, 05/15, 09/15, 09/16, 09/17, 09/18
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Diabetes can lead to microvascular and macrovascular complications and poor quality of life when not managed properly. In recent years, new antidiabetic agents have been released which improve the convenience of managing diabetes appropriately. HPSJ has adopted the treatment goals and recommendations of the most recent American Diabetes Association (ADA) Standards of Care for the treatment of diabetes, including treating to a goal of hemoglobin A1c (HbA1c) <7%. The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents and to help members reach target HbA1c levels.

Table 1. Oral Anti-Diabetic Agents *(Current as of 3/2019)*

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	HbA1c % Decrease	Average Cost per 30 days	Notes
Single Agents						
Biguanides	**Metformin (Glucophage)**	500mg, 850mg, 1000mg	QL	1.5% - 2%	$1.43	500mg = limit of 5 per day 850mg = limit of 3 per day 1000mg = limit of 2 per day
	Metformin ER (Glucophage XR)	500mg, 750mg	QL		$2.14	Uses dual hydrophilic polymer matrix system. 500mg = limit of 5 per day 750mg = limit of 3 per day
	Metformin ER (Fortamet ER)	500mg, 1000mg	NF		$237.06	Uses single-composition osmotic technology.
	Metformin ER (Glumetza)	500mg, 1000mg	NF		$3969.36	Uses gastric retention technology.
	Metformin Solution (Riomet)	500mg/5ml	NF		--	--
Sulfonylureas	**Glipizide (Glucotrol)**	5mg, 10mg	--	1% - 2%	$2.03	--
	Glipizide ER (Glucotrol XL)	2.5mg, 5mg, 10mg	--		$8.97	--
	Glimepiride (Amaryl)	1mg, 2mg, 4mg	--		$3.64	--
	Glyburide (Diabeta)	1.25mg, 2.5mg, 5mg	--		$6.87	--
	Chlorpropamide	100mg, 250mg	--		$55.15	--
Meglitinides	**Nateglinide (Starlix)**	60mg, 120mg	NF	0.5% - 1.5%	$70.25	--
	Repaglinide (Prandin)	0.5mg, 1mg, 2mg	NF		--	--
TZD	**Pioglitazone (Actos)**	15mg, 30mg, 45mg	ST; QL	1.5% - 2%	$5.01	Contraindicated in patients with CHF. Limit of one tablet per day
α-glucosidase Inhibitors	**Acarbose (Precose)**	50mg, 100mg	--	0.5% - 1%	$31.47	--
DPP-IV Inhibitors	**Sitagliptin (Januvia)**	25mg, 50mg, 100mg	ST; QL; PA*	0.5% - 0.8%	$435.64	*PA required for 25mg and 50mg dose. Limit of one tablet per day.
	Saxagliptin (Onglyza)	2.5mg, 5mg	PA; QL		$422.26	Patients must have tried and failed Januvia, Tradjenta, Nesina. Limit of one tablet per day.
	Linagliptin (Tradjenta)	5mg	ST; QL		$417.09	Limit of one tablet per day.
	Alogliptin (Nesina)	6.25mg, 12.5mg, 25mg	PA; QL		--	Patients must have tried and failed Januvia, Tradjenta. Limit of one tablet per day.

ST = Step therapy to Metformin; QL = Quantity Limit; PA = Prior Authorization Required; NF = Non-Formulary; HbA1c = Hemoglobin HbA1c; DPP-4 = Dipeptidyl Peptidase 4; TZD = Thiazolidinedione; SGLT-2 = Sodium Glucose Cotransporter-2; ER = Extended Release

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	HbA1c % Decrease	Average Cost per 30 days	Notes
SGLT-2 Inhibitors	**Empagliflozin (Jardiance)**	10mg, 15mg	ST; QL	0.5% - 1%	$477.13	Limit of one tablet per day.
	Ertugliflozin (Steglatro)	5mg, 25mg	ST; QL		$285.83	Limit of one tablet per day.
	Canagliflozin (Invokana)	100mg, 300mg	ST; QL		$472.25	Patients must have tried and failed Empagliflozin or Ertugliflozin. Limit of one tablet per day.
	Dapagliflozin (Farxiga)	5mg, 10mg	ST; QL		$467.05	
Combination Agents						
Sulfonylureas	**Glipizide/Metformin**	2.5mg-250mg, 2.5mg-500mg, 5mg-500mg	--	*See above*	$31.73	
	Glyburide/Metformin (Glucovance)	2.5mg-250mg, 5mg-500mg, 2.5mg-500mg	--	*See above*	$5.62	--
TZD	**Pioglitazone/Metformin (Actoplus Met)**	15mg-500mg, 15mg-850mg	QL	*See above*	$80.92	Limit of three tablets per day.
	Pioglitazone/Metformin XR (Actoplus Met XR)	15mg-1000mg, 30mg-1000mg	QL		$652.10	Limit of two tablets per day.
	Pioglitazone/Glimepiride (Duetact)	30mg-2mg 30mg-4mg	NF	--	--	--
DPP-4	**Sitagliptin/Metformin (Janumet)**	50mg-500mg, 50mg-1000mg	QL	*See above*	$425.54	Limit of two tablets per day.
	Sitagliptin/Metformin XR (Janumet XR)	50mg-500mg, 50mg-1000mg, 100mg-1000mg	QL		$396.64	Limit of two tablets per day. (Except 100-1000mg)
	Saxagliptin/Metformin XR (Kombiglyze XR)	5mg-500mg, 5mg-1000mg, 2.5mg-1000mg	PA; QL		$407.18	Patients must fail Januvia, Tradjenta AND Nesina. Limit of one tablet per day. (Except 2.5-1000mg – limit 2 tablets per day)
	Linagliptin/Metformin (Jentadueto)	2.5mg-500mg, 2.5mg-850mg, 2.5mg-1000mg	QL		$407.90	Limit of 2 tablets per day.
	Linagliptin/Metformin XR (Jentadueto XR)	2.5mg-1000mg 5mg-1000mg	QL		$356.77	Limit of 1 tablet per day. (Except 2.5mg-1000mg – limit 2 tablets per day)
	Alogliptin/Metformin (Kazano)	12.5mg-500mg 12.5mg-1000mg	PA; QL	--	--	Patients must fail Januvia AND Tradjenta. Limited to 2 tablets per day.
SGLT-2 Inhibitors	**Empagliflozin/Metformin (Synjardy)**	5mg-500mg, 5mg-1000mg, 12.5-500mg, 12.5mg-1000mg	QL	*See above*	$445.96	Limit of 2 tablets per day.
	Empagliflozin/Metformin XR (Synjardy XR)	5mg-1000mg, 12.5mg-1000mg	QL		$377.96	Limit of 2 tablets per day.
		10mg-1000mg, 25mg-1000mg				Limit of 1 tablet per day.
	Ertugliflozin/Metformin (Segluromet)	2.5mg-500mg, 2.5mg-1000mg, 7.5mg-500mg, 7.5mg-1000mg	--		$246.94	
	Canagliflozin/Metformin (Invokamet)	50mg-500mg, 50mg-1000mg, 150-500mg, 150mg-1000mg	ST, QL		$467.39	Patients must have tried and failed metformin and Empagliflozin or Ertugliflozin. Limit of 2 tablets per day.
	Canagliflozin/Metformin ER (Invokamet XR)	50mg-500mg, 50mg-1000mg, 150-500mg, 150mg-1000mg	ST, QL		$439.16	
	Dapagliflozin/Metformin XR (Xigduo XR)	5mg-500mg, 5mg-1000mg	ST, QL		$473.83	Patients must have tried and failed metformin and Empagliflozin or Ertugliflozin. Limit of 2 tablets per day.
		10mg-500mg, 10mg-1000mg			$473.83	Patients must have tried and failed metformin and Empagliflozin or Ertugliflozin. Limit of 1 tablet per day.
	Dapagliflozin/Metformin (Xigduo)	5mg-500 mg, 5mg-1000mg, 10mg-500mg, 10mg-1000mg	NF	--	--	--
	Empagliflozin/Linagliptin (Glyxambi)	10mg-5mg, 25mg-5mg	NF	--	--	--

ST = Step therapy to Metformin; QL = Quantity Limit; PA = Prior Authorization Required; NF = Non-Formulary; HbA1c = Hemoglobin HbA1c; DPP-4 = Dipeptidyl Peptidase 4; TZD = Thiazolidinedione; SGLT-2 = Sodium Glucose Cotransporter-2; ER = Extended Release

Table 2. Inhalable/Injectable Anti-Diabetic Agents *(Current as of 3/2019)*

Therapeutic Class	Drug Name	Available Strengths	Limit	Cost/Rx	Notes
Rapid Acting Insulins	Insulin Lispro (Admelog)	100 U/ml vial	--	$348.56	
		100 U/ml pen	QL	$365.30	Limit 1 box per 30 days. For patients requiring >1 box per month, submit PA indicating insulin dose/frequency.
	Insulin Lispro (Humalog)	100 U/ml	NF	$399.68	
		200 U/ml	NF	$1,281.77	
	Insulin Glulisine (Apidra)	100 U/ml	QL	$479.21	Pens limited to 1 box per 60 days. For patients requiring >1 box per 60 days, submit PA indicating insulin dose/frequency.
	Insulin Aspart (Novolog, Fiasp)	100 U/ml		$464.69	
Intermediate Acting Insulins	Human Insulin NPH (Humulin N, Novolin N)	100 U/ml		$219.57	
Long Acting Insulins	Insulin Glargine (Basaglar)	100 U/mL		$245.80	Limit 1 box per 30 days. For patients requiring >1 box per month, submit PA indicating insulin dose/frequency.
	Insulin Glargine (Toujeo, Toujeo Max)	300 U/ml	PA	$781.68	Restricted for patients requiring >80 units per insulin injection.
	Insulin Glargine (Lantus)	100 U/ml	NF	$351.38	
	Insulin Detemir (Levemir)	100 U/ml	NF	$447.18	
	Insulin Degludec (Tresiba)	100 U/ml	NF	$297.76	
		200 U/ml	NF	$383.39	
Short Acting Insulins	Regular Insulin (Humulin R, Novolin R)	100 U/ml vial	--	$193.26	
	Regular Insulin (Humulin R Kwikpen U-500)	500 U/ml	PA	$1,364.41	
	Regular Insulin (Humulin R Vial U-500)	500 U/ml	NF	$1,516.74	
Insulin Mixtures	Human Insulin NPH/Regular Insulin (Humulin 70-30, Novolin 70-30)	70-30 U/ml	NF	$313.08	
	Insulin Aspart Protamine/Insulin Aspart (Novolog Mix 70-30)	70-30 U/ml	QL	$616.02	Pens limited to 1 box per 60 days. For patients requiring >1 box per 60 days, submit PA indicating insulin dose/frequency.
	Insulin Lispro Protamine/Insulin Lispro (Humalog Mix 75-25)	72-25 U/ml		$703.00	
	Insulin Lispro Protamine/Insulin Lispro (Humalog Mix 50-50)	50-50 U/ml	NF	$865.62	
GLP-1 Agonists	Semaglutide (Ozempic)	0.25mg/0.5ml pen, 1 mg/ml pen	PA	$619.27	Patients must have tried and failed Jardiance and Invokana, have HgbA1c <10%, and have two visits with a dietician.
	Liraglutide (Victoza)	18mg/3ml pen	PA	$738.99	Patients must have tried and failed Jardiance, Invokana, and Ozempic, have HgbA1c <10%, and have two visits with a dietician.
	Exenatide (Byetta)	5mcg/dose; 10mcg/dose	PA	$725.36	Patients must have tried and failed Jardiance, Invokana, Ozempic, and Victoza, have HgbA1c <10%, and have two visits with a dietician.
	Exenatide ER (Bydureon, Bydureon BCise)	2mg/pen 2mg/0.85ml pen		$678.55	
	Dulaglutide (Trulicity)	0.75mg/0.5ml pen 1.5mg/0.5ml pen	NF	$734.47	
Amylin Analogues	Pramlintide Acetate (Symlin Pen)	1500mcg/1.5mL 2700 mcg/2.7mL	PA	$2,178.65	Restricted to obese patients with inadequate response to optimal insulin therapy (basal and meal coverage with HbA1c < 9 and BMI > 30.

Inhalable Rapid-Acting Insulin	**Afrezza**	4 unit, 8 unit, 12 unit cartridges	PA	--	Reserved for treatment failure to two dose-optimized rapid-acting injectable insulin (3 months each) in patients with normal FEV1 values.
QL = Quantity Limit; PA = Prior Authorization Required; NF = Non-Formulary; ST = Step Therapy					

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Biguanide Single-Agent Products

Metformin, Metformin ER (Glucophage XR, Fortamet ER, Glumetza)

- **Coverage Criteria:** None
- **Limits:**
  - 500mg IR(generic Glucophage) tablet: Max 5 tablets/day
  - 850mg IR tablet (generic Glucophage): Max 3 tablets/day
  - 1000mg IR tablet (generic Glucophage): Max 75 per 30 days
  - 500mg ER (generic of Glucophage XR): Max 5 tablets/day
  - 750mg ER (generic of Glucophage XR): Max 3 tablets/day
- **Required Information for Approval:** N/A
- **Other Notes:** Use of Metformin Extended Release (ER) is encouraged due to the lower incidence of gastrointestinal side effects such as diarrhea, nausea and bloating.
- **Non Formulary:** Glumetza, Riomet, Fortamet ER 500mg, 1000mg

Thiazolidinediones (TZD) Single-Agent Products

Actos (Pioglitazone)

- **Coverage Criteria:** Pioglitazone is step therapy to inadequate response to an adequate trial of Metformin, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects.
- **Limits:** 1 tablet per day
- **Required Information for Approval:**
  - History of Metformin fills
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c
- **Other Notes:**
  - Rosiglitazone is non-formulary.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Januvia (Sitagliptin); Onglyza (Saxagliptin); Tradjenta (Linagliptin); Nesina (Alogliptin)

Januvia (Sitagliptin), Tradjenta (Linagliptin)

- **Coverage Criteria:** Januvia/Tradjenta is step therapy to inadequate response to an adequate and concurrent trial of metformin, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects.
- **Limits:** 1 tablet per day
- **Required Information for Approval:**
  - History of Metformin fills
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c
- **Other notes:**
  - Januvia 25mg and 50mg are only to be used when renal function declines below 50 ml/min/m^2. Standard dosing is 100mg daily for renal function that is greater than 50 ml/min/m^2.
  - There is no benefit to twice-daily dosing of this class of medication, as inhibition of the DPP-4 enzyme lasts a full 24 hours.

Nesina (Alogliptin)

- ❒ **Coverage Criteria:** Alogliptin is reserved for inadequate response to an adequate and concurrent trial of metformin, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects. Alogliptin is reserved for patients who have tried and failed both Januvia and Tradjenta.
- ❒ **Limits:** 1 tablet per day
- ❒ **Required Information for Approval:**
  - History of Metformin, Januvia, and Tradjenta fills
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c
- ❒ **Other notes:**
  - Nesina 12.5mg is only to be used when renal function is between 30 to <60 ml/min/m^2. Nesina 6.25mg daily is used when renal function is less than 30 ml/min/m^2. Standard dosing is 25mg daily for Nesina.
  - There is no benefit to twice-daily dosing of this class of medication, as inhibition of the DPP-4 enzyme lasts a full 24 hours.

Onglyza (Saxagliptin)

- ❒ **Coverage Criteria:** Onglyza is reserved for inadequate response to an adequate and concurrent trial of metformin, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects. Onglyza is reserved for patients who have tried and failed Januvia, Tradjenta and Nesina.
- ❒ **Limits:** 1 tablet per day
- ❒ **Required Information for Approval:**
  - History of Metformin, Januvia, Tradjenta, and Nesina fills
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c
- ❒ **Other notes:**
  - Onglyza 2.5mg is only to be used when renal function declines below 50 ml/min/m^2. Standard dosing is 5mg daily for Onglyza.
  - There is no benefit to twice-daily dosing of this class of medication, as inhibition of the DPP-4 enzyme lasts a full 24 hours.

Sodium Glucose Cotransporter-2 (SGLT-2) Inhibitors
Invokana (Canagliflozin); Farxiga (Dapagliflozin); Jardiance (Empagliflozin); Steglatro (Ertugliflozin)

- ❒ **Coverage Criteria:**
  - **Jardiance and Steglatro** are step therapy to inadequate response to an adequate and concurrent trial of metformin, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects.
  - **Invokana and Farxiga** are step therapy to inadequate response to an adequate and concurrent trial of metformin **AND** Jardiance or Steglatro, unless intolerant or contraindicated. A documented trial of Metformin Extended-Release is required if metformin cannot be tolerated due to gastrointestinal side effects.
- ❒ **Limits:** 1 tablet per day
- ❒ **Required Information for Approval:**
  - History of Metformin fills AND fills of Empagliflozin (Jardiance) or Ertugliflozin (Steglatro)
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c

Combination products
Glyburide/Metformin (Glucovance); Pioglitazone/Metformin (Actoplus Met); Pioglitazone/Metformin XR (Actoplus Met XR); Sitagliptin/Metformin (Janumet); Sitagliptin/Metformin XR (Janumet XR); Saxagliptin/Metformin XR (Kombiglyze XR); Linagliptan/Metformin (Jentadueto); Linagliptan/Metformin XR (Jentadueto XR); Alogliptin/Metformin (Nesina); Alogliptin/Pioglitazone (Oseni); Pioglitazone/Glimepiride (Duetact);

Canagliflozin/Metformin (Invokamet); Dapagliflozin/Metformin (Xigduo); Dapagliflozin/Metformin XR (Xigduo XR); Empagliflozin/Metformin (Synjardy); Empagliflozin/Metformin XR (Synjardy XR); Ertugliflozin/Metformin (Segluromet)

- ❒ **Coverage Criteria:**
  - Janumet, Janumet XR, Jentadueto, Jentadueto XR, Synjardy, Synjardy XR, Segluromet: None
  - Alogliptin/Metformin (Kazano): Alogliptin/Metformin is reserved for patients who have tried and failed both Januvia and Tradjenta.
  - Saxagliptin/Metformin (Kombiglyze XR): Saxagltipin/Metformin is reserved for patients who have tried and failed Januvia, Tradjenta, and Nesina.
  - Invokamet IR/XR, Xigduo XR is step therapy to an adequate trial of metformin and Empagliflozin or Ertugliflozin, unless intolerant/contraindicated.
- ❒ **Limits:**
  - Glyburide/Metformin (Glucovance) - None
  - Pioglitazone/Metformin (Actoplus Met) - Limited to 3 tablets per day
  - Pioglitazone/Metformin XR (Actoplus Met XR) – Limited to 2 tablets per day
  - Sitagliptin/Metformin (Janumet) – Limited to 2 tablets per day
  - Sitagliptin/Metformin XR (Janumet XR) – Limited to 2 tablets per day
  - Alogliptin/Metformin IR (Kazano) – Limited to 2 tablets per day
  - Saxagliptin/Metformin XR (Kombiglyze XR)
    - 2.5mg-1000mg - Limited to 2 tablets per day
    - 5mg-500mg, 5mg-1000mg – Limited to 1 tablet per day
  - Linagliptan/Metformin (Jentadueto) – Limited to 2 tablets per day
  - Linagliptan/Metformin XR (Jentadueto XR)
    - 2.5mg-1000mg - Limited of 2 tablets per day
    - 5mg-1000mg – Limited to 1 tablet per day
  - Canagliflozin/Metformin (Invokamet) - Limited to 2 tablets per day
  - Canagliflozin/Metformin ER (Invokamet XR) – Limited to 2 tablets per day
  - Dapagliflozin/Metformin XR (Xigduo XR) –
    - 5mg-500mg, 5mg-1000mg - Limited to 2 tablets per day
    - 10mg-500mg, 10mg-1000mg – Limited to 1 tablet per day
  - Empagliflozin/Metformin (Synjardy) – Limited to 2 tablets per day
  - Empagliflozin/Metformin XR (Synjardy XR) –
    - 5mg-1000mg, 12.5mg-1000mg - Limited to 2 tablets per day
    - 10mg-1000mg, 25mg-1000mg – Limited to 1 tablet per day
- ❒ **Required Information for Approval**
  - **Kazano (Alogliptin/Metformin):**
    - Clinical documentation of adverse reaction and severity (if applicable)
    - Fill history of metformin and Linagliptin (Tradjenta) and Sitagliptin (Januvia)
  - **Kombiglyze XR (Saxagliptin/Metformin):**
    - Clinical documentation of adverse reaction and severity (if applicable)
    - Fill history of metformin and Linagliptin (Tradjenta) and Sitagliptin (Januvia) and Alogliptin (Nesina)
  - **Invokamet IR/XR, Xigduo XR:**
    - Clinical documentation of adverse reaction and severity (if applicable)
    - Fill history of metformin and Empagliflozin (Jardiance) or Ertugliflozin (Steglatro)
- ❒ **Non Formulary -** Alogliptin/Pioglitazone (Oseni), Pioglitazone/Glimepiride (Duetact), Dapagliflozin/Metformin (Xigduo)

Sulfonylureas

Glipizide (Glucotrol); Glipizide ER/XL (Glucotrol ER/XL); Glimepiride (Amaryl); Glyburide (Diabeta);

- ❒ **Coverage Criteria:** NONE
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** N/A

α-glucosidase Inhibitors

Acarbose (Precose)

- ❒ **Coverage Criteria:** NONE
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** N/A

Insulins

Vials *[Insulin Aspart (Novolog, Fiasp); Insulin Lispro (Humalog); Insulin Regular (Humulin R, Novolin R), Insulin Isohpane (Humulin N, Novolin N); Insulin Glulisine (Apidra)]*

- ❒ **Coverage Criteria:** NONE
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** N/A
- ❒ **Non-Formulary:** Levemir Vials, Humulin R U-500 Vials, Lantus Vials, Humalog Mix 50-50 Vials, Novolin 70-30 Vials

Pens *(Humalog Kwikpen, Novolog Flexpen, Humalog Mix 75-25, Novolog Mix 70-30 Flexpen, Humulin 70-30 Kwikpen, Tresiba, Humulin R U-500 Kwikpen, Basaglar Kwikpen, Toujeo Solostar, Toujeo Max Solostar)*

- ❒ **Coverage Criteria:**
  - Humulin R U-500 Kwikpen: PA required. Reserved for patients requiring more than 200 units of insulin per day.
  - Toujeo Solostar, Toujeo Max Solostar: PA required. Toujeo is reserved for patients requiring more than 80 units of insulin glargine per injection.
- ❒ **Limits:**
  - Admelog, Basaglar: 1 box per 30 days
  - Novolog, Fiasp, Apidra, Humulin N, Humulin 70-30, Novolog Mix 70-30,: 1 box per 60 days
  - Exception: No quantity limit on Humulin R U-500 Kwikpen, Toujeo Solostar, or Toujeo Max Solostar
- ❒ **Required Information for Approval:** For patients requiring more than 1 box of insulin per 60 days, submit prior authorization indicating insulin regimen.
- ❒ **Non-Formulary:** Levemir Flexpen, Apidra Solostar, Humalog U-200 Kwikpen, Tresiba, Lantus Solostar, Humalog Kwikpen, Novolin 70-30 Kwikpen, Humalog Mix 50-50 Kwikpen

Incretin Mimetics (GLP-1 agonists)

Exenatide (Byetta / Bydureon), Liraglutide (Victoza), Semaglutide (Ozempic)

- ❒ **Coverage Criteria:**
  - **Ozempic**: PA required. Reserved for an inadequate response to 3 months of compliant use of dose-optimized Metformin with Jardiance AND metformin with Invokana (unless intolerant or contraindicated) with A1c <10%. A trial of Metformin ER is required if intolerance is GI-related. Patients must also have received exercise and dietary counseling at least twice by a registered dietician.
  - **Victoza**: PA required. Reserved for an inadequate response to 3 months of compliant use of dose-optimized Metformin with Jardiance AND metformin with Invokana (unless intolerant or contraindicated) AND Ozempic with A1c <10%. A trial of Metformin ER is required if intolerance is GI-related. Patients must also have received exercise and dietary counseling at least twice by a registered dietician.
  - **Byetta/Bydureon/Bydureon BCise:** PA required. Reserved for an inadequate response to 3 months of compliant use of dose-optimized Metformin with Jardiance AND metformin with Invokana (unless intolerant or contraindicated) AND Ozempic AND Victoza with A1c <10%. A trial of Metformin ER is required if intolerance is GI-related. Patients must also have received exercise and dietary counseling at least twice by a registered dietician.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:**
  - History of Metformin, Jardiance, Invokana, Ozempic, Victoza trial
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c
  - Documentation of exercise and dietary counseling at least twice by a registered dietician
- ❒ **Non-Formulary:** Trulicity, Tanzeum, Adlyxin

Amylinomimetics

Pramlintide Acetate (Symlin)

- ❒ **Coverage Criteria:** Symlin is step therapy to inadequate response to optimal insulin therapy (basal and meal coverage) in obese patients with HbA1c < 9 and BMI > 30.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:**
  - History of Metformin fills
  - Clinical documentation of adverse reaction and severity (if applicable)
  - Renal Function
  - Most recent HbA1c

Inhaled Insulin

Afrezza

- ❒ **Coverage Criteria:** Reserved for treatment failure to two dose-optimized rapid-acting injectable insulin (3 months each) in patients with normal baseline FEV1 values.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:**
  - History of 2 of the following insulins: Humalog, Novolog, Apidra fills (3 months each)
  - Pulmonary Function Tests (PFTs) indicating normal FEV1 values
  - HbA1c
- ❒ **Required Information for Renewal:**
  - Most recent HbA1c
  - Annual PFTs
    - A decline in FEV1 by ≥ 20% will prompt discontinuation of Afrezza

Glucagon

Glucagon Emergency 1mg Injection Kit

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** None.
- ❒ **Non Formulary:** Glucagon 1mg solution (reconstituted).

Diabetic Supplies

A. HPSJ requires the use of the preferred meter and test strips (manufactured by Fora) for all members.
   1. Members who are new starts with HPSJ who have a pre-existing insulin pump may continue to use the same meter/strips as they were previous to coverage with HPSJ.

B. A prescription is required from a licensed provider for coverage of diabetes testing supplies.

C. The following quantity limits apply
   1. **Test Strips:**
      a. Non-insulin dependent: 100 strips per 30 days (3 per day)
      b. Insulin dependent: 150 per 30 days (5 per day)
      c. Larger amounts of test strips will require documentation of reason for and planned duration of additional daily testing
   2. **Lancets** - 100 lancets per 30 days (3 per day)
   3. **Lancing device** - 1 device every 12 months
   4. **Glucometer** - 1 device per lifetime
   5. **Alcohol pads** - 100 pads per 30 days
   6. **Insulin Syringes** - 200 per 30 days
   7. **Control Solution** - 1 bottle per 12 months

D. A maximum of 30 days of test strips may be dispensed

⌗ Clinical Justification:

Metformin has a long-proven history of efficacy and safety. It can be used to reduce insulin dependence and has one of the best HbA1c reductions of the oral agents. It also reduces cardiovascular morbidity and mortality. With this in mind, HPSJ has set formulary positioning to reflect this. An adequate trial of, and adherence to Metformin is required for use of any other oral antidiabetic agents. Metformin Extended Release has a much lower incidence of

side effects, when compared to Metformin Immediate Release, therefore an adequate trial of dose-optimized Metformin Extended Release is required (unless contraindicated due to renal function) before other oral agents can be approved as monotherapy.

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Diabetes Class Review 11-06.doc	11/2006	Allen Shek, PharmD
Update to Policy	Diabetes Class Review 11-27-07.doc	11/2007	Allen Shek, PharmD
Update to Policy	Diabetes Class Review 11-17-09.doc	11/2009	Allen Shek, PharmD
Update to Policy	Diabetes Class Review 2-15-11.docx	2/2011	Allen Shek, PharmD
Update to Policy	Diabetes Class Review 5-15-2012.docx	5/2012	Allen Shek, PharmD
Update to Policy	Diabetes Class Review 9-16-14.docx	9/2014	Jonathan Szkotak, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Diabetes 2015-05.docx	9/2015	Jonathan Szkotak, PharmD, BCACP
Update to Policy	HPSJ Coverage Policy – Endocrine – Diabetes 2016-09.docx	9/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Diabetes 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Diabetes 2018-09.docx	9/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Diabetes 2019-05.docx	5/2019	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy