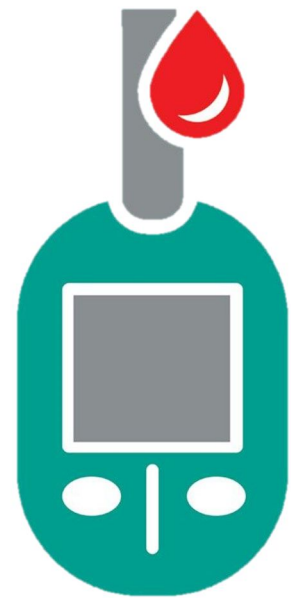


Provider Toolkit:

Type 2 Diabetes Mellitus



Provider Toolkit:

Type 2 Diabetes Mellitus

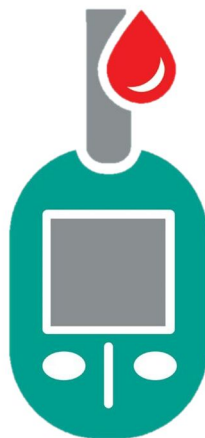
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Diabetes Mellitus Type 2 Clinical Pathway– Primary Care Strategy

Key Words:

- Diabetes Mellitus Type 2
- Primary Care

Target Audience:

This policy applies to the following organizations:

- Kootenai Care Network, participating clinics
- Kootenai Health Ambulatory Clinics
- Kootenai Health Outpatient Services

Objective:

The purpose of this policy is to provide an evidence based guideline for the treatment of type 2 diabetes mellitus patients. It is our goal that this policy will:

- Improve patient safety
- Promote evidence based, guideline adherent, and mechanisms cognizant diabetes management
- Promote prompt diagnosis, effective assessment and appropriate treatment of type 2 diabetes
- Better manage pharmaceutical spend within Kootenai Care Network, including patient's pharmacy spend
- Facilitate discovery of comorbid conditions contributing to symptoms
- Improve standardization of diabetes treatment practices in order to make our expectations for our patients more transparent, improve accountability for patients, and increase consistency for staff protocols.

Patient Population:

This policy provides the guidelines for management of type 2 diabetes mellitus.

Patient inclusion criteria –

This policy covers diagnoses including but not limited to:

- Adult age ≥ 18 years, pre-diabetes
- Adult age ≥ 18 years, type 2 diabetes



Rationale and Background:

According to the CDC National Diabetes Report in 2017, \$327 billion were spent in total costs of diagnosed diabetes in the United States in 2017. \$237 billion was for direct medical costs and \$90 billion for reduced productivity. After adjusting for population age and sex differences, the average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes.

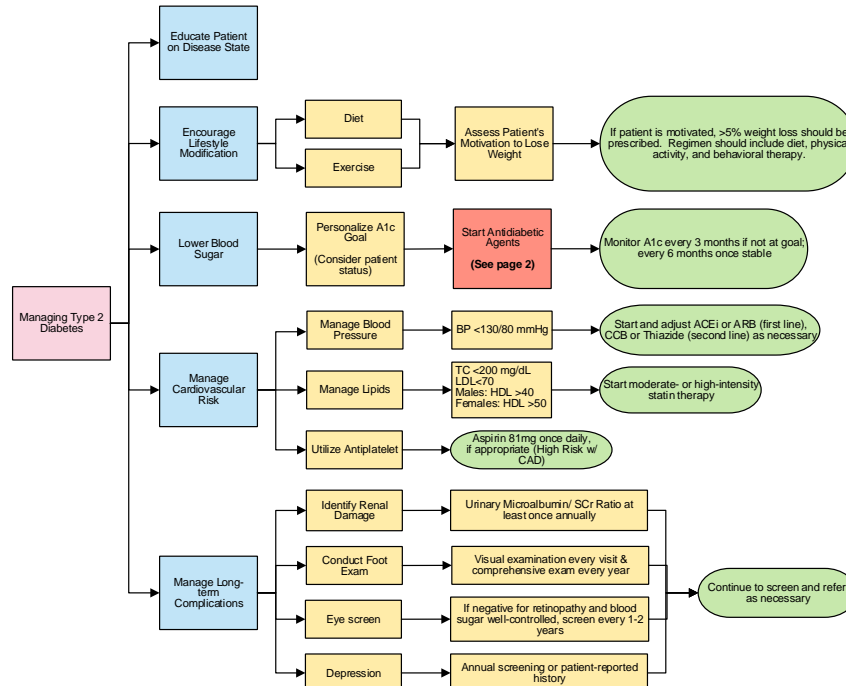
Approximately 1.5 million Americans are diagnosed with diabetes every year. And in 2015, 84.1 million Americans age 18 and older had prediabetes. And even with advances in diabetes treatment options and education about healthy lifestyles and nutrition, diabetes remains the 7th leading cause of death in the United States.

Our goal is to create a pathway that promotes improved processes of care, ensures timely diagnosis and treatment decisions that are both based on evidence-based medicine and that are made jointly with the patient, and that improve the health outcomes of patients with diabetes in your community.

Clinical Algorithms:

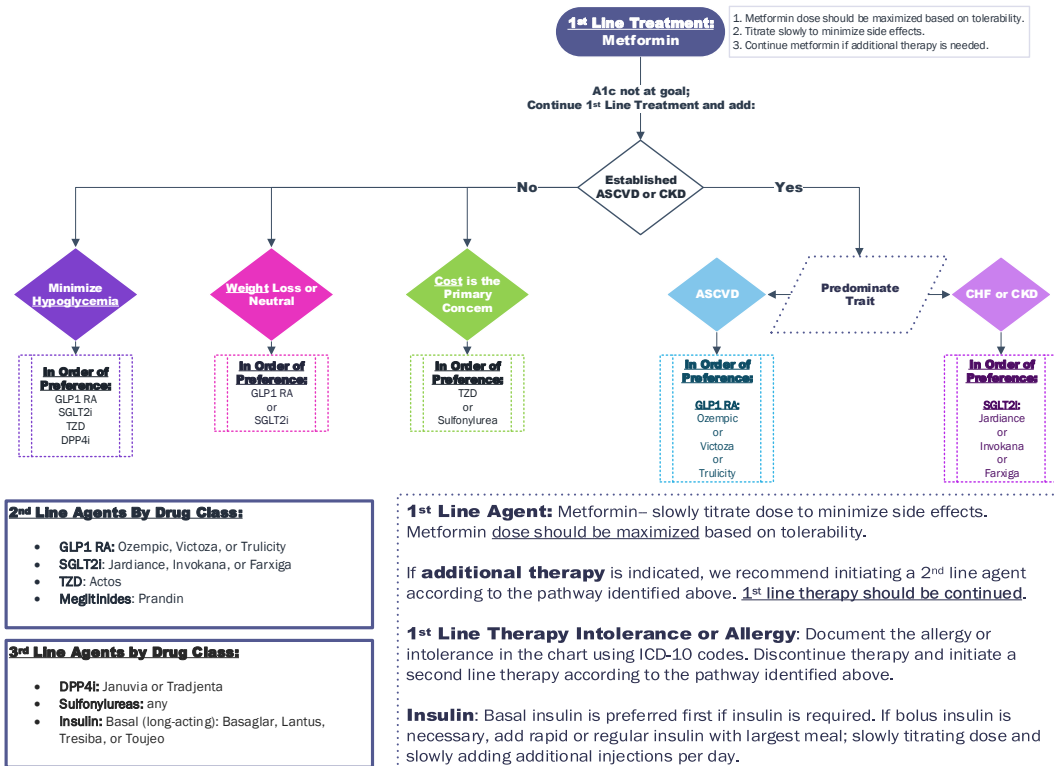
Type 2 Diabetes Mellitus Management Clinical Pathway

(2019)




Type 2 Diabetes Mellitus Pharmacotherapy Clinical Pathway

(2019)


References/Supporting Evidence:

- American College of Cardiology: Endorses ADA 2019 Standards of Care
- American Association of Clinical Endocrinology/ American College of Endocrinology: AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019
- American Diabetes Association 2019 Standards of Medical Care in Diabetes

Implementation & Education Items:
Implementation:

- KCN Quality Committee approval
- KCN Board approval
- Primary Care Service Line presentation

Supporting Documents: Diabetes Provider Toolkit

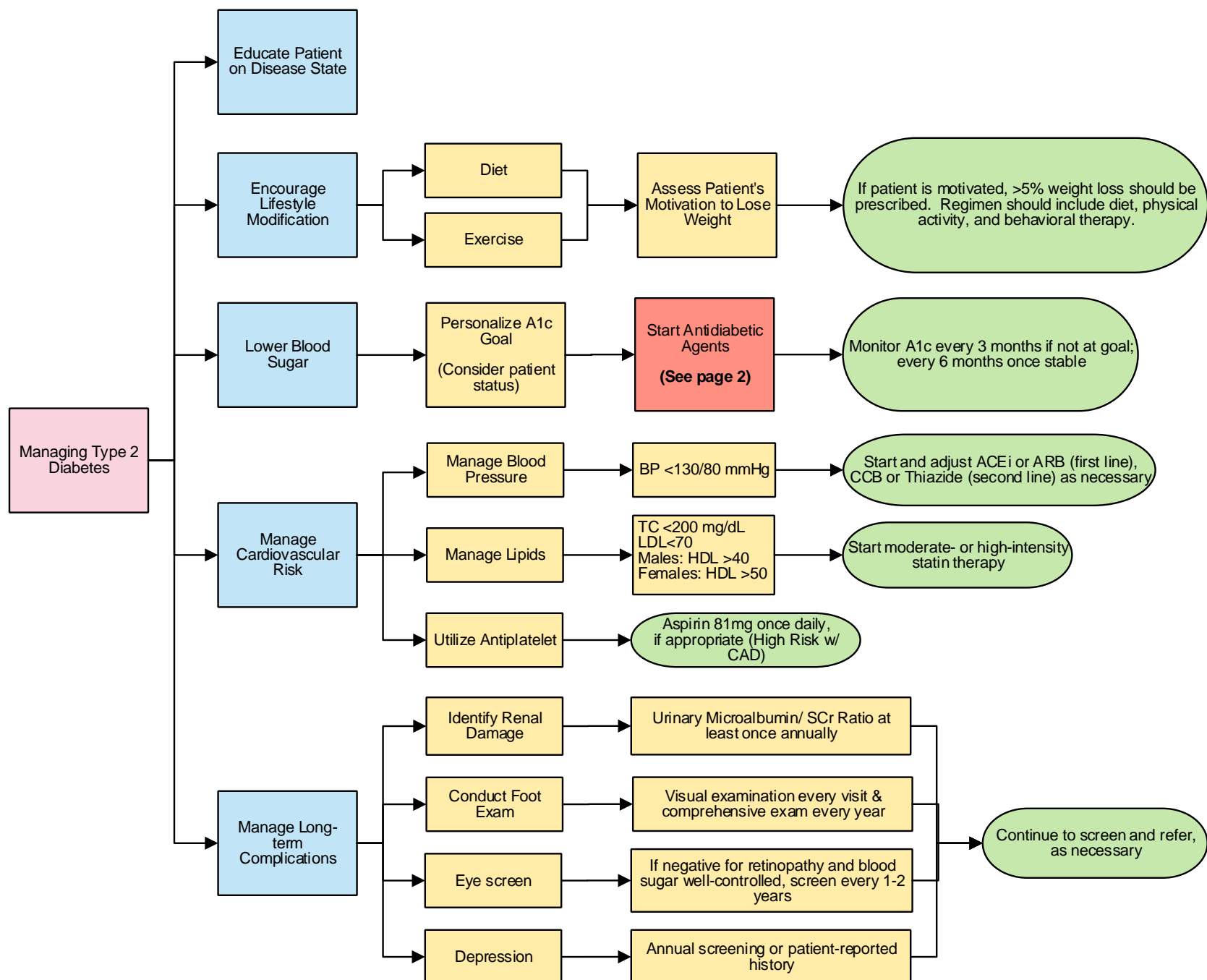
- Type 2 Diabetes Mellitus Clinical Pathway Algorithm
- Type 2 Diabetes Mellitus Pharmacotherapy Clinical Pathway Algorithm
- Recommended Type 2 Diabetes Mellitus Medications Cost by Formulary Tier
- Coverage Gap Information
- Cost Savings Strategies for Insulin
- Injectable Diabetes Mellitus Medication Dispensing Reference Guide

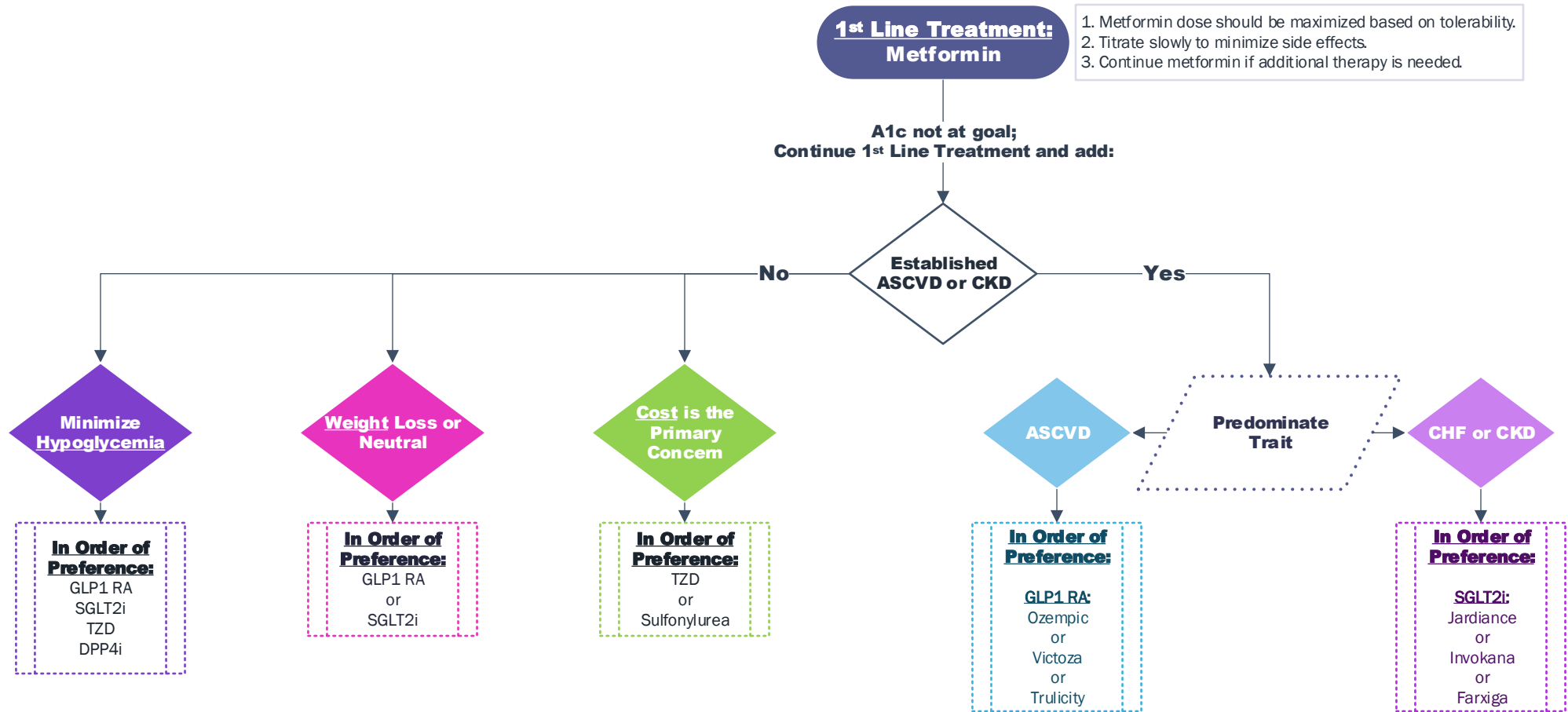


| | |
|---|--|
| Kootenai Care Network Applications <ul style="list-style-type: none"> Provision of Continuing Education | |
| <u>Quality Metrics Plan:</u> ACO# 27: Diabetes Mellitus: Hemoglobin A1c Poor Control (> 9%) <ul style="list-style-type: none"> Percentage of patients 18 - 75 years of age with diabetes who had hemoglobin A1c > 9% during the measurement period. Lower score indicates better quality. | |
| <u>Quality Plan, Do, Study, Act (PDSA) Plan:</u> The Kootenai Care Network will be responsible for ongoing review of the literature and for developing necessary modifications to the clinical pathway based on published or local best practices. The guideline will be formally reviewed annually. | |
| <u>Point of Contact:</u> Created in collaboration with KCN Diabetes Workgroup; endocrinologist Maria Rodebaugh, MD; family medicine practitioner Jonathan Shupe, MD; Shelly Rutledge, PharmD; and KCN Quality Committee. Contact: Shelley Janke, KCN Director of Quality and Care Management | |
| <u>Distribution:</u> Kootenai Care Network | |
| <u>Approval By:</u> KCN Diabetes Workgroup KCN Quality Committee KCN Board | <u>Date of Approval:</u> 05/2019 05/2019 06/2019 |
| <u>Original Date:</u> 05/2019 | <u>Revision Dates:</u> |

Type 2 Diabetes Mellitus Management Clinical Pathway

(2019)





2nd Line Agents By Drug Class:

- **GLP1 RA:** Ozempic, Victoza, or Trulicity
- **SGLT2i:** Jardiance, Invokana, or Farxiga
- **TZD:** Actos
- **Meglitinides:** Prandin

3rd Line Agents by Drug Class:

- **DPP4i:** Januvia or Tradjenta
- **Sulfonylureas:** any
- **Insulin:** Basal (long-acting): Basaglar, Lantus, Tresiba, or Toujeo

1st Line Agent: Metformin– slowly titrate dose to minimize side effects. Metformin dose should be maximized based on tolerability.

If **additional therapy** is indicated, we recommend initiating a 2nd line agent according to the pathway identified above. 1st line therapy should be continued.

1st Line Therapy Intolerance or Allergy: Document the allergy or intolerance in the chart using ICD-10 codes. Discontinue therapy and initiate a second line therapy according to the pathway identified above.

Insulin: Basal insulin is preferred first if insulin is required. If bolus insulin is necessary, add rapid or regular insulin with largest meal; slowly titrating dose and slowly adding additional injections per day.

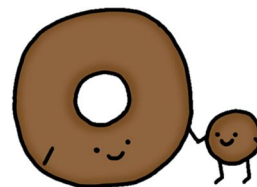
Recommended Diabetes Medications by Formulary Tier (05/2019)

| Recommended | Drugs | | PS MA | BCI KH | BCI QHP | BCI MA | Regence MA | Kaiser Commercial |
|----------------------|---------------|---|------------------------|---|---|-----------------------|---------------------------|------------------------|
| | | | Est. Cost (Tier) | Est. Cost (Tier) | Est. Cost (Tier)) | Est. Cost (Tier) | Est. Cost (Tier) | Est. Cost (Tier) |
| 1 st Line | Biguanide | Glucophage Metformin | \$0 (6) | \$10 (1) | \$10 (1) | \$0 (1) | \$3 (1) | \$25 (1) |
| 2 nd Line | GLP1i | ^ Victoza Liraglutide | \$37 (3); QL | \$30 (2); ST; QL | \$30 (3); ST; QL | \$37 (3); QL | \$40 (3); QL | 50% (3); QL; ST |
| | | Ozempic Semaglutide | \$37 (3) | \$30 (2); ST; QL | \$30 (3); ST; QL | \$37 (3); QL | \$40 (3); QL | 50% (3); QL; PA |
| | SGLT2i | ^ Jardiance Empagliflozin | \$37 (4); QL | \$30 (2); ST | \$30 (3); ST | \$37 (3); QL | \$40 (3); QL | 40% (2); QL; PA |
| | Meglitinides | Starlix Nateglinide | \$0 (6); G | \$10 (1) | \$10 (1) | \$0 (1); QL | \$13 (2) | 50% (3) |
| | | Prandin Repaglinide | \$0 (6); G | \$10 (1) | \$10 (1) | \$0 (1); QL | \$13 (2) | 50% (3) |
| | TZD | Actos Pioglitazone | \$0 (6); G | \$10 (1) | \$10 (1) | \$0 (1); QL | \$13 (2) | 50% (3) |
| 3 rd Line | DPP4i | ^ Januvia Sitagliptin | \$37 (3); QL | \$30 (2); ST | \$30 (3); ST | \$37 (3); QL | \$40 (3); QL | 50% (3); PA |
| | Sulfonylureas | Majority drugs in class | \$0 (6) | \$10 (1) | \$10 (1) | \$0 (1) | \$3 (1) | \$25 (1) |
| | Insulin | Metformin should be continued even if insulin is initiated. | \$37 (3); G ^Lantus | \$30 (2) ^Lantus, ^Toujeo, Tresiba | \$30 (3) ^Lantus, ^Toujeo, Tresiba | \$37 (3) ^Basaglar | \$40 (3); QL - ^Lantus | 40% (2) ^Lantus |
| | | Basal usually preferred first when initiating. | \$37 (3) ^Toujeo | | | \$37 (3) ^Levemir | \$40 (3); QL - ^Toujeo | 50% (3) PA- ^Toujeo |
| | | If needed, Basal plus meal-time insulin. | \$37 (3) Tresiba | | | | \$40 (3); QL - Tresiba | 50% (3) PA- Tresiba |
| | | | | | | | | |

| | | | |
|--------|--------------------|-------------------------|---------------------------------|
| Legend | G= Gap Coverage | PA= Prior Authorization | ST= Step Therapy Required |
| | QL= Quantity Limit | | ^= Patient Assistance Potential |

| |
|---|
| Additional Information: |
| * Recommendations: Based on evidence-based outcomes, payer formulary, and spend |
| ** Estimated cost: based on using preferred pharmacies (highest copay observed=listed) |
| *** Gap Coverage= Continue paying regular copay during the coverage gap |

Disclaimer: Although the data have been produced from resources believed to be reliable, Kootenai Care Network provides this information on an "as is" basis and takes no responsibility for the timeliness, accuracy, completeness or quality of the information provided. Kootenai Care Network does not warrant that any information or material provided will be error-free or omission-free.



Coverage Gap Information

What is the Coverage Gap?

After you and your insurance have paid \$3,820 in 2019 for prescription medicines, you will enter the coverage gap, also known as the donut hole. While in the donut hole you will pay 25% of the cost for brand name medicines and 37% of the cost for generic medicines. Once you spend \$5,100 you will exit the donut hole.

| | |
|---------------------------|---|
| Coverage Gap explanation: | https://medicare.com/medicare-part-d/coverage-gap-donut-hole-made-simple |
|---------------------------|---|

Pick the Right Medicare Part D Plan

Make sure to check your insurance's medicine formulary every year for changes in coverage.

How to find a plan online:

| | |
|----------------------|---|
| Medicare plan finder | https://www.medicare.gov/find-a-plan/questions/home.aspx |
|----------------------|---|

Where to Get Additional Help:

1) SHIBA

- Senior Health Insurance Benefits Advisors (SHIBA) is a local service who help patients by offering free, unbiased Medicare benefits information and assistance through workshops, group presentations and personal counseling.
- <https://doi.idaho.gov/SHIBA/default>
- Phone number: 1-800-247-4422

2) Low Income Subsidy Information

- Make sure you apply for low income subsidy if you need additional help paying for your medicines.
- More Information: <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/index.html>

3) Extra Help

- Your resources must be limited to \$14,390 for individuals or \$28,720 married.
 - Includes such things as bank accounts, stocks, and bonds
- Your annual income must be limited to \$18,735 for individual or \$25,365 married
- How to Apply:
 - On-line at: <https://secure.ssa.gov/i1020/Ee006bView.action>
 - Local Social Security office
 - By calling 1-800-772-1213 (TTY 1-800-325-0778) to apply over the phone or to request an application
- More about extra help: <https://www.ssa.gov/pubs/EN-05-10525.pdf>

4) Patient Assistance:

- Patient assistance may be available while you are in the donut hole if you are not qualified for Extra Help
- <https://www.medicare.gov/pharmaceutical-assistance-program/Index.aspx#>

Cost Saving Strategies for Insulin

Step 1: Utilize KCN Recommended Diabetes Clinical Pathway and Formulary Tier Chart

Step 2: Refer to Patient Assistance Resources

Provider Tools

- **Rx Assist** | www.rxassist.org
 - Searchable database which lists patient assistance programs for specific medications.
 - Patient and Provider friendly
- **Medication Assistance Tool** | www.medicineassistancetool.org
 - Search engine for specific medications and the patient assistance programs available.
 - Patient and Provider friendly
- **Paramount Rx** | www.paramountrx.com
 - Drug discount card
 - Searchable database of current cash prices for specific medications
 - Patient and Provider friendly
- **Needy Meds** | www.needymeds.org
 - Searchable database for specific medications which yields information on coupons/rebates, patient assistance programs, and copay cards
 - Patient and Provider friendly

Patient Specific Tools

- **Benefits Check Up** | www.benefitscheckup.org
 - Provided by the National Council on Aging that allows older patients to answer a few questions to develop an individualized report on benefits programs for which they qualify in the following areas: prescription drug assistance, health care, rent, utilities and other needs.
- **Blink Health** | www.blinkhealth.com
 - Website for patients to view discounted prices and if they opt to use this service, they have to pay for the medication online through the Blink Health website and they provide the patient with the pharmacy billing information.
- **FamilyWize** | www.familywize.org | 1-800-222-2818
 - Offers discounted prices for many medications and provides information on available assistance programs.
- **Inside Rx** | www.insiderx.com
 - Drug discount card
 - Searchable database of current discount prices for specific medications
- **SingleCare** | www.singlecare.com
 - Drug discount card
 - Searchable database of current discount prices for specific medications
- **GoodRx** | www.goodrx.com
 - Drug discount card
 - Searchable database of current discount prices for specific medications

References:

American Diabetes Association: <http://www.diabetes.org/living-with-diabetes/health-insurance/prescription-assistance.html>

JAMA Article titled Frequency of Sale and Reasons for Purchase of Over-the-Counter Insulin in the United States (2019) | Goldstein JN, Patel RM, Bland K, Hicks LS. Frequency of Sale and Reasons for Purchase of Over-the-Counter Insulin in the United States. JAMA Intern Med. 2019;179(5):722–723. doi:10.1001/jamainternmed.2018.7279

Cost Saving Strategies for Insulin

Step 3: Insulin Without a Prescription

(Use with CAUTION)

Available OTC insulins include: Novolin and Humulin both NPH and Regular

- **Walmart Brand ReliOn Novolins** are the cheapest options at **\$24.88** per 10 mL vial
 - Available ReliOn formulations: Novolin R, Novolin N, and Novolin 70/30
- Other pharmacies provide this option as well; however, the cash price is ~\$160

Additional Information

Double copays

- Can result if a patient's insulin prescription exceeds the insurers' quantity limit cutoff (each policy has varying cutoffs)
 - *Example:* a patient uses 40 units/day and a box of 5 insulin pens contains 1500 units which is a 37-day supply. If this patient's insurance plan cutoff is 30 days, this would trigger a 60-day co-pay (usually double the cost).

Cheap glucose meters and test strips

- Can be purchased from most retail pharmacies for their "store brand" products
 - *Example:* Walmart ReliOn brand
 - Glucometer \$9
 - Test Strips (100 count) \$18
 - Lancets (100 count) \$2
 - Lancing Device \$6

Mail Order

- Some insurance companies provided cost savings if the patient utilizes mail order services.
- Consider mail order as a possible alternative
- Most mail orders provided medicines in 90-day supplies.

References:

American Diabetes Association: <http://www.diabetes.org/living-with-diabetes/health-insurance/prescription-assistance.html>

JAMA Article titled Frequency of Sale and Reasons for Purchase of Over-the-Counter Insulin in the United States (2019) | Goldstein JN, Patel RM, Bland K, Hicks LS. Frequency of Sale and Reasons for Purchase of Over-the-Counter Insulin in the United States. JAMA Intern Med. 2019;179(5):722–723. doi:10.1001/jamainternmed.2018.7279

Injectable Diabetes Medication Dispensing Reference Guide

Prescribing Tips

- Remember to include the maximum daily or maximum specified dose prescribed in the SIG line in order to calculate the day supply; "inject per sliding scale" alone is not valid.
 - ie: Inject up to 25 units subcutaneously nightly at bedtime or Inject 12-20 units subcutaneously three times daily before meals.
- Remember Pens are usually dispensed by box not by number of pens. Try to prescribe units as close to 30, 60, or 90 day supplies as possible in order to increase medication adherence and decrease patient co-pays.
 - Day supply is required by insurance companies, which directly correlate to patient adherence measures.

| Injectable Diabetic Medications | Concentration | Contents | Units or mg per box | Max daily dose <i>per one box</i> for 30 days |
|---------------------------------------|----------------------|-------------------------------------|------------------------|---|
| GLP-1 (dosed in mg) | | | | |
| Victoza (2 pack) | 6 mg/mL | 6 mL/box (2 pens of 3 mL) | 36 mg/box | 1.2 mg per day |
| Victoza (3 pack) | 6 mg/mL | 9 mL/box (3 pens of 3 mL) | 54 mg/box | 1.8 mg per day |
| Ozempic | 1.34 mg/mL | 1.5mL/box (1 pen of 1.5 mL) | 2 mg/box | 0.25 mg x4 wk 0.5 mg x4 wk |
| Ozempic (2 pack) | 1.34 mg/mL | 3 mL/box (2 pens of 1.5 mL) | 4 mg/box (4 doses) | 1 mg per week |
| Trulicity | 0.75 mg/0.5 mL | 2 mL/box (4 pens of 0.5 mL) | 3 mg/box (4 doses) | 0.75 mg per week |
| Trulicity | 1.5 mg/0.5 mL | 2 mL/box (4 pens of 0.5 mL) | 6 mg/box (4 doses) | 1.5 mg per week |
| Byetta | 250 mcg/mL | 1.3 mL/box (1 pen of 1.2 mL) | 300 mcg/box (60 doses) | 5 mg BID |
| Byetta | 250 mcg/mL | 2.4 mL/box (1 pen of 2.4 mL) | 600 mcg/box (60 doses) | 10 mg BID |
| Bydureon | 2 mg/0.65 mL | 2.6 mL/box (4 pens of 0.65 mL) | 8 mg/box (4 doses) | 2 mg per week |
| Aspart (Rapid Acting) | | | | |
| Novolog | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Novolog FlexPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Glulisine (Rapid Acting) | | | | |
| Apidra | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Apidra SoloStar | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Lispro (Rapid Acting) | | | | |
| Humalog | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humalog KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Humalog KwikPen Jr. | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | Dosed in 0.5 (½) units |
| Regular Insulin (Short Acting) | | | | |
| Humulin R | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Novolin R | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humulin R | 500 units/mL | 20 mL/vial | 10000 units | 333 units (0.66 mL) |
| Humulin R KwikPen | 500 units/mL | 6 mL (2 pens of 3 mL) | 3000 units | 100 units (0.2 mL) |

Injectable Diabetic Medication Quick Reference Guide

| NPH Insulin (Intermediate Acting) | | | | |
|---|---------------------|----------------------------------|------------|--------------------|
| Humulin N | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Novolin N | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humulin N KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Insulin Glargine (Long Acting) | | | | |
| Lantus | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Lantus SoloStar | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Basaglar KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Toujeo SoloStar | 300 units/mL | 4.5 mL/box (3 pens of 1.5 mL) | 1350 units | 45 units (0.15 mL) |
| Toujeo Max SoloStar | 300 units/mL | 6 mL/box (2 pens of 3 mL) | 1800 units | 60 units (0.2 mL) |
| Insulin Detemir (Long Acting) | | | | |
| Levemir | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Levemir FlexTouch | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Insulin Degludec (Ultra Long Acting) | | | | |
| Tresiba | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Tresiba | 200 units/mL | 9 mL/box (3 pens of 3 mL) | 1800 units | 60 units (0.3 mL) |
| Combination Products | | | | |
| Regular/ NPH | | | | |
| Humulin 70/30 | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Novolin 70/30 | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humulin 70/30 KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Humulin Mix 50/50 | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humulin Mix 50/50 KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Aspart/ Aspart Protamine | | | | |
| Novolog 70/30 | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Novolog 70/30 FlexPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Lispro/ Lispro protamine | | | | |
| Humalog 75/25 | 100 units/mL | 10 mL/vial | 1000 units | 33 units (0.33 mL) |
| Humalog 75/25 KwikPen | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |
| Insulin Degludec/ Aspart | | | | |
| Ryzodeg 70/30 FlexTouch | 100 units/mL | 15 mL/box (5 pens of 3 mL) | 1500 units | 50 units (0.5 mL) |