PNRR SOP for Metabolic Syndrome Evaluation Form

Standard Operating Procedure for
Metabolic Syndrome Evaluation Form (MetSyn)

Subject ID: subject ID is populated automatically.

I. HYPERGLYCEMIA

HbA1C value entered in the PNW file is displayed

1. **Diagnosis of hyperglycemia:**

   - **Yes:** patient fulfills one of these criteria:
     i. Recorded clinical diagnosis of Diabetes Mellitus type 1 or type 2,
     ii. Recorded clinical diagnosis of impaired glucose tolerance (IGT),
     iii. past impaired fasting glucose (IFG) of ≥100 mg/dL (with confirmed fasting),
     iv. past HbA1C ≥5.7%,
     v. past elevated 2-hour blood glucose levels ≥140 mg/dL during Oral Glucose Tolerance Test
   - **No:** patient does not have a diagnosis of DM type 1 or 2, or diagnosis of prediabetes
   - **Unknown:** should only be chosen if no fasting glucose or HbA1C laboratory testing results are available and no medical history is entered into EPIC and medication intake is not verified

2. **Type/severity of hyperglycemia:**

   - **Pre-diabetes:** patient fulfills one of these criteria:
     i. has diagnosis of IGT (2-hr glucose ≥140, but <200 mg/dL),
     ii. past IFG (≥100 but ≤125 mg/dL) was confirmed fasting,
     iii. elevated current or past HbA1c (≥5.7, but never >6.4),
     iv. does not take any other glycemic control medications besides metformin,
     v. enrolling physician indicates that patient has prediabetes in exam note
   - **DM Type 2:** patient fulfills one of these criteria:
     i. past HbA1C of ≥6.4%,
     ii. past IFG >125 mg/dL with confirmed fasting,
     iii. taking ≥1000 mg Metformin QD, or
     iv. taking any other medication to treat hyperglycemia besides metformin
   - **DM Type 1:** patient carrying diagnosis of DM type 1
   - **Unknown:** should only be selected if no information is available in regard to type of hyperglycemia

Depending on which type of hyperglycemia was selected, questions 3 and 4 will be tailored towards the type of hyperglycemia. If DM Type 1 is selected, question 3 does not appear because DM Type 1 patients have to use insulin.

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3.a Medications taken by patient for Pre-diabetes:

- **No medications:** patient does not take any medications to control blood sugar levels.
- **Low dose Metformin:** patient takes Metformin 500 mg QD or BID, but no other medications to control blood sugar levels.
- **Unknown:** daily medication intake is unknown

If patient takes any other hyperglycemia-controlling medications on a regular basis, the "type/severity of hyperglycemia" data entry should be changed to DM type 2 (or possibly type 1 if the medication is insulin)

3.b Medications taken by patient for DM type 2:

- **No medications:** patient does not take medication for hyperglycemia
- **Metformin only:** hyperglycemia is controlled with only taking metformin; no other medications regularly prescribed to lower blood sugar levels
- **Metformin and other medications (not insulin):** patient takes metformin and at least one more medication to lower blood sugar levels, but patient is not prescribed insulin
- **Insulin (and other hyperglycemic medications):** patient has prescription of at least one insulin-containing medication.
- **Unknown:** medication prescriptions are unknown

Common Diabetes / Prediabetes Medications:

Brand Name	Generic Name	Indication
Actos	Piglitazone	Prediabetes or DM type 2
Alogliptin	Alogliptin	DM type 2
Amaryl	Glimepiride	DM type 2
Bydureon, Byetta	Exenatide	DM type 2
Diabeta	Glyburide	DM type 2
Farxiga	dapfliflozin	DM type 2
Glucotrol	Glipizide	DM type 2
Glumetza	Metformin hydrochloride	DM type 2
Humalog	Insulin lispro	DM type 2
Invokana	Canagliflozin	DM type 2
Janumet	Sitagliptin and metformin	DM type 1 or DM type 2
Januvia	Sitagliptin	DM type 2
Jardiance	Empagliflozin	DM type 2
Lantus, Basaglar, Toujeo	Insulin glargine	DM type 2
Levemir	Insulin detemir	DM type 2

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Novolin N, Humulin N	Insulin N	DM type 2
Novolin R, Humulin R	Insulin R	DM type 2
Novolog	Insulin aspart	DM type 1 or DM type 2
Onglyza	Saxagliptin	DM type 2
Ozempic	Semaglutide	DM type 2
Prandin	Repaglinide	DM type 2
Semglee	insulin glargine-yfgn	DM type 2
Starlix	Nateglinide	DM type 2
Symlin Pen	Pramlinitide	DM1
Tradjenta	Linagliptin	DM type 2
Tresiba	Insulin Degludec	DM type 1 or DM type 2
Trulicity	Dulaglutide	Prediabetes or DM type 2
Victoza, Saxenda	Liraglutide	DM type 2

4. Time elapsed since patient was diagnosed with diabetes or prediabetes:

Number of years to be entered, with one decimal, e.g 5.5 years
If information is not available in the medical records, patient should be asked to estimate the time since his/her diagnosis and that information should be entered (e.g. patient answer "at least 6 years", 6.0 should be entered
Enter "unknown" if information is not available – this option only applies when information is backfilled for older records.

5. Patient's medical complications from diabetes or pre-diabetic hyperglycemia:

To be checked if the patient has medical record evidence of each diagnosis, regardless of when it was diagnosed with regard to the onset of hyperglycemia

- **None:** patient has none of the diagnosis on records, takes no medication to treat any of the conditions and lab testing results are in normal range
- **Renal insufficiency:** to be checked if patient fulfills one of the following criteria:
    - i.   entered creatinine level is above 1.3 mg/dL,
    - ii. glomerular filtration rate (GFR) <60 mL/min/1.73m^2,
    - iii. patient has diagnosis of kidney or renal failure on record,
    - iv. patient takes medication to treat renal failure
- **Retinal, macular or lens-based eye disease:**
    - i.   patient has diagnosis of retinopathy, macular edema, or cataracts (or past cataracts surgeries),
- **Coronary artery disease:**
    - i.   patient has diagnosis of coronary artery disease (CAD), atherosclerosis, angina or arrhythmia,
    - ii. patient had past heart attack, stent or bypass surgeries

       iii. patient takes medications to treat CAD
- **Vasculopathy:**
    - i. patient carries diagnosis of common vascular disorders such as deep vein thrombosis (DVT), stroke, pulmonary embolus (PE), peripheral arterial disease (PAD), or livedoid vasculopathy
    - ii. patient takes medication to treat vasculopathy.
- **Unknown:** information not available

Glaucoma

Name	Generic Name
Betaxolol	n/a
Betimol	Timolol
Betoptic	Betaxolol
Bimatroprost	n/a
Istalol	Timolol
Latanoprost	n/a
Latanoprostene	n/a
Lumigan	Bimatroprost
Tafluprost	n/a
Timolol	n/a
Timoptic	Timolol
Travatan	Travoprost
Travoprost	n/a
Vyzulta	Latanoprostene
Xalatan	Latanoprost
Zioptan	Tafluprost

Coronary Artery Disease

Name	Generic Name
Aspirin (>81 mg)	n/a
Clopidogrel	n/a
Eptifibatide	n/a
Integrilin	Eptifibatide
Nitroglycerin	n/a
Plavix	Clopidogrel
Ranolazine	n/a
Ticlid	Ticlopidine
Ticlopidine	n/a

Renal Insufficiency

Name	Generic Name
Demadex	Torsemide
Edecrin	Ethacrynic acid
Ethacrynic acid	n/a
Furosemide	n/a
Lasix	Furosemide
Torsemide	n/a
Sodium Edecrin	Ethacrynic acid

Vasculopathy

Name	Generic Name
Apixaban	n/a
Atrixtra	Fondaparinux
Betrixaban	n/a
BEVYXXA	Betrixaban
Coumadin	Warfarin
Dabigatran	n/a
Edoxaban	n/a
Eliquis	Apixaban
Fondaparinux	n/a
Heparin	n/a
Pentoxifylline	n/a
Pradaxa	Dabigatran
Rivaroxaban	n/a
Savaysa	Edoxaban
Trentol	Pentoxifylline
Warfarin	n/a
Xarelto	Rivaroxaban

6. **Physician assessment of glycemic control:**

For new enrollments, the enrolling physician should provide this assessment. For past enrollments, the following criteria should be used if no assessment about hyperglycemic control can be found in the medical records:
- Well controlled: HbA1c consistently <7.0

- Moderately controlled: HbA1c 7.0 - 9.0
- Poorly controlled: past HbA1c >9.0
- Unknown: should only be used if no past HbA1c information can be found in the medical records.

7. **Past HbA1C testing:**

Past glycemic haemoglobin (HbA1c) values should be entered as available together with the year of testing. Ideally, past HbA1c testing should provide information about the glycemic control history of the patient – if glycemic control fluctuated over the years, the entered values should reflect this.   If patients have a long-standing diagnosis of diabetes, the entered HbA1c values should span the entire duration (e.g. if a patient has DM type 2 for the past 10 years, then ideally, HbA1c from 4, 7 and 10 years ago would be entered – plus the most recent HbA1c value entered in the PNW file).

II. HYPERTENSION

1. **Medication(s) taken by patient for hypertension:**

- **None:** patient does not take any blood pressure lowering drugs
- **One HTN medication:** patient takes one blood pressure lowering drug
- **Two HTN medications:** patient takes two blood pressure lowering drugs
- **Three or more HTN medications:** patient takes three or more blood pressure lowering drugs
- **Unknown:** medication prescriptions are unknown. Unknown should not be entered for new enrollments, only when information is backfilled for older enrollment records.

Medications routinely prescribed to treat hypertension:

Brand Name	Generic Name		Brand Name	Generic Name
Sectral	Acebutolol		Prinivil, Zestril	Lisinopril
Aldactazide	Aldactone + HCTZ		Cozaar	Losartan
Tekturna	Aliskiren		Toprol XL	Metoprolol Succinate
Tenormin	Atenolol		Lopressor	Metoprolol Tartrate
Edarbi	Azilsartan		Corgard	Nadolol
Lotensin	Benazepril		Bystolic	Nebivolol
Bumex	Bumetanide		Procardia, Adalat	Nifedipine
Atacand	Candesartan		Inderal	Propranolol
Coreg	Carvedilol		Accupril	Quinapril
Hygroton	Chlorthalidone		Altace	Ramipril
Catapres	Clonidine		Aldactone	Spironolactone

Cardiazem, Tiazac, Dilacor	Diltiazem		Micardis	Telmisartan
Cardura	Doxazosin		Dyrenium	Triamterene
Vasotec	Enalapril		Dyazide, Maxide	Triamterene + HCTZ
Monopril	Fosinopril		Diovan	Valsartan
Lasix	Furosemide		Micardis	Telmisartan
Apresoline	Hydralazine		Verelan, Calan	Verapamil
Avapro	Irbesartan			

2. **Systolic BP on day of PNRR visit:**

Systolic blood pressure reading on the day of visit in mmHg, or within 3 months of visit if blood pressure was not measured at the actual visit date.

3. **Diastolic BP on day of PNRR visit:**

Diastolic blood pressure reading on the day of visit in mmHg, or within 3 months of visit if blood pressure was not measured at the actual visit date.

III. OVERWEIGHT / OBESITY

BMI, calculated from entered weight and height in PEF file is displayed

1. **Is the patient overweight or obese?**

- **No:** patient has a BMI <27
- **Yes, overweight (BMI ≥27)**
- **Yes, obese (BMI ≥30)**
- **Unknown:** patient has no BMI or height/weight information on record. This option is for older enrollments when MetSyn data is backfilled and information cannot be obtained through medical records or by asking the patient.

For patients who are considered obese, both "obese" and "overweight" should be checked and time elapse since diagnosis should be provided for both conditions. If a patient is considered obese, both years of being obese and years of being overweight should be captured if possible.

2.a Years since patient was diagnosed as being overweight

Number of years to be entered, e.g. 33 years. If, based on record review or participant recall, the absolute time is unknown, but a minimal time overweight can be confidently stated (e.g. "at least 10 years", this should be provided.
Enter "unknown" if information is not available.

2.b Years since patient was diagnosed as being obese

Number of years to be entered, e.g. 33 years. If, based on record review or participant recall, the absolute time is unknown, but a minimal time obese can be confidently stated (e.g. "at least 10 years", this should be provided
Enter "unknown" if information is not available.

BMI calculator:
Can be utilized to calculate BMI based on past weight measurements found in the medical records to determine when patients was first considered overweight or obese. Calculator automatically uses height entered in PEF file.

IV. DYSLIPIDEMIA

Triglycerides and high-density cholesterol (HDL) testing results are displayed if they were previously entered into the PNW file.

1. **Diagnosis of Dyslipidemia:**

   - **Yes:** patient fulfills at least one of the following criteria:
     - i.   patient has hypertriglyceridemia (triglycerides >150mg/dL),
     - ii. patient has abnormal low high density cholesterol (HDL) levels (for men <40mg/dL, for women <50mg/dL), or
     - iii. patient takes triglyceride-lowering medication, or
     - iv. patient takes high dosage of lipid-lowering drugs (statins)
   - **No:** patient does have normal lipid profile and take lower dosages of lipid-lowering drugs as usually prescribed for hypercholesteremia
   - **Unknown:** not feasible to determine if patient has dyslipidemia based on the available information

2. **Type of dyslipidemia diagnosed in patient:**

   - **Elevated triglycerides (>150):** patient had elevated triglycerides of >150 mg/dL in at least one lipid profile during the past 36 months
   - **Low HDL levels (<40 for men, <50 for women):** patient had low HDL level in at least one lipid profile during the past 36 months
   - **Takes triglyceride-lowering medication:** patient takes triglyceride lowering agent
   - **Takes low intensity statin dose:** see table below
   - **Takes high intensity statin dose:** see table below or if patient takes multiple agents
   - **Unknown:** neither lipid profile nor medication list is available for this patient

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3. Does patient take statin?
If question of diagnosis of dyslipidemia is answered negatively or as unknown, pop-up question appears asking for use of statin.
- **No:** patient does not take statin
- **Yes, low intensity statin dose:** prescription is listed as low dosage in table below
- **Yes, high intensity statin dose:** prescription is listed as high dosage in table below
- **Unknown:** information not available (only applies to old enrollment records)

Lipid-lowering agents – low and high dosages

Generic Name	Brand Name	Low dosage	High Dosage
Atorvastatin	Lipitor	10-20 mg	40-80 mg
Fluvastatin	Lescol	20-40 mg	80 mg
Lovastatin	Mevacor Altoprev	10-40 mg	60-80 mg
Pravastatin	Pravachol	10-40 mg	80 mg
Rosuvastatin	Crestor	5-10 mg	20-40 mg
Simvastatin	Zocor	5-40 mg	80 mg

Triglyceride lowering agents

Generic Name	Brand Name	
Bezafibrate	Bezalip	
Ezetimibe	Zetia	
Fenofibrate	Antara Fenoglide Lipofen Tricor Triglide	
Fenofibric acid	Fibricor Trilipix	
Gemfibrozil	Lopid	***Note:** for patients taking Niacin or Omega-3 fatty acids, it should be confirmed that they are taking it to lower their triglyceride levels and not for other reasons such as heart health if triglyceride levels in lipid panel are in normal range.
Icosapent ethyl	Vascepa	
Niacin*	Vitamin B3	
Omega-3 fatty acids*		

V. EXERCISE

1. Does the patient exercise?
- **Yes:** The activity should be identified as being performed as exercise, rather than, for instance, as a part of the patient's work activity, yard chores, or housekeeping.
- **No:** patient does not exercise.
- **Unknown:** no information available about exercise habits of this patient.

2. Total number of minutes exercising per week:

Minutes of exercises per week reported by patient – total of all exercises (including aerobic exercise). If patient reports different weekly exercising routines, the average per week should be reported.

3. **Total number of minutes of aerobic exercise per week:**
    Time the patient is performing aerobic exercises, such as jogging, power walking, treadmill, stationary bike, elliptical, swimming, water gymnastics or aerobics. Activities during which the patient "breaks a light sweat" or is a little short of breath are considered aerobic exercise. The weekly average the patient spends on performing aerobic exercises should be reported.