Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Hypoglycemics, Insulin and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemics, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin and Related Agents at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For a non-preferred Hypoglycemics, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

   a. Has a diagnosis of type 1 or type 2 diabetes mellitus; **AND**

   b. Has a documented history of contraindication or intolerance to the preferred Hypoglycemics, Insulin and Related Agents that would not be expected to occur with the requested medication

   AND

2. For Afrezza, whether the beneficiary:

   a. Is 18 years of age or older; **AND**

   b. Is prescribed the medication by or in consultation with an endocrinologist; **AND**

   c. Has a documented history of therapeutic failure, contraindication, or intolerance to short- and rapid-acting injectable Hypoglycemics, Insulin and Related Agents; **AND**

   d. Has been evaluated for lung function, including a documented detailed medical history, physical examination, and spirometry testing; **AND**

   e. Does not have any contraindications to Afrezza; **AND**

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f. Does not have active lung cancer or a history of lung cancer; **AND**

g. Has a documented medical history of abstinence from smoking for at least 6 months and is not currently a smoker; **AND**

h. Will be assessed for lung function using spirometry testing six (6) months after initiating Afrezza and annually thereafter; **AND**

i. Has a documented baseline hemoglobin A1c (HbA1c); **AND**

j. For type 1 diabetes mellitus, will be using Afrezza in conjunction with a long-acting insulin

OR

k. For type 2 diabetes mellitus, has a documented history of:

i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin in combination with maximum tolerated doses of the second line agents used to treat type 2 diabetes in accordance with the most recent American Diabetes Association (ADA) guidelines; **OR**

ii. A contraindication or intolerance to metformin and the second line agents used to treat type 2 diabetes in accordance with the most recent ADA guidelines

AND

3. For a Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

a. Has a diagnosis of type 2 diabetes mellitus; **AND**

b. Has a documented history of:

i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin

OR

ii. A contraindication or intolerance to metformin

AND

iii. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using basal insulin

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OR

iv. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using a GLP-1 receptor agonist

AND

c. Will not be using the requested agent in combination with any other product containing a GLP-1 receptor agonist; **AND**

d. For a non-preferred agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Hypoglycemics, Insulin and Related Agents combination agent that contains a GLP-1 receptor agonist

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR HYPOGLYCEMICS, INSULIN AND RELATED AGENTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Hypoglycemics, Insulin and Related Agents that were previously approved will take into account the following:

1. For Afrezza, whether the beneficiary:

    a. Has improved glycemic control as evidenced by a recent documented HbA1c value; **AND**

    b. Is prescribed the medication by or in consultation with an endocrinologist; **AND**

    c. Has been evaluated for lung function using spirometry testing approximately 6 months after starting Afrezza, and, if applicable, annually thereafter; **AND**

    d. Did not have a decline in FEV_1 of >20% from baseline since starting Afrezza; **AND**

    e. Has a documented medical history of abstinence from smoking for at least 6 months and is not currently a smoker; **AND**

    f. Does not have any contraindications to Afrezza; **AND**

    g. Does not have active lung cancer; **AND**

    h. Did not experience any bronchospasm, wheezing, or other respiratory difficulties after using Afrezza

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AND

2. For a Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

    a. Has improved glycemic control as evidenced by a recent HbA1c value; **AND**

    b. Will not be using the requested agent in combination with any other product containing a GLP-1 receptor agonist

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemics, Insulin and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Gateway Health

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SOLIQUA and XULTOPHY (GLP-1 receptor agonist/insulin combinations) PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	total # of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Drug requested:	☐Soliqua	☐Xultophy	☐_____
Directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Does the beneficiary have a diagnosis of type 2 diabetes?	☐Yes – *Submit documentation of diagnosis.* ☐No – *Submit medical literature supporting the use of the requested medication for the beneficiary's diagnosis.*
Does the beneficiary have a history of trial and failure of, or contraindication or intolerance to, maximum tolerated doses of metformin?	☐Yes ☐No *Submit documentation of treatment regimen tried and HbA1c results or contraindication or intolerance.*
Did the beneficiary fail to achieve glycemic goals with basal insulin (e.g., Lantus, Levemir) and/or a GLP-1 receptor agonist (e.g., Byetta, Bydureon, Trulicity, Victoza)?	☐Yes ☐No *Submit documentation of treatment regimen tried and HbA1c results.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: