lt's Wholecare.

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

I. Requirements for Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers

A. Prescriptions That Require Prior Authorization

All prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

- Is prescribed the Hypoglycemic, Incretin Mimetic/Enhancer for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to treat obesity; AND
- 2. For a glucagon-like peptide-1 (GLP-1) receptor agonist or dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, has a documented history of **one** of the following:
 - a. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin,
 - b. A contraindication or intolerance to metformin,
 - Requires initial dual therapy with metformin based on HbA1c as defined by the American Diabetes Association or the American Association of Clinical Endocrinologists and American College of Endocrinology,
 - d. For a GLP-1 receptor agonist or DPP-4 inhibitor with proven cardiovascular disease (CVD), heart failure (HF), or chronic kidney disease (CKD) benefit, has CVD (or two risk factors for CVD as identified by the American Diabetes Association or the American Association of Clinical Endocrinologists and American College of Endocrinology), HF, or CKD;

AND

- For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer, has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers at: https://papdl.com/preferred-drug-list; AND
- 4. For an amylin analog, **all** of the following:
 - a. For a diagnosis of type 2 diabetes mellitus, has a documented history of **one** of the following:



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- i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin
- ii. A contraindication or intolerance to metformin,
- Failed to achieve adequate glycemic control as evidenced by the beneficiary's HbA1c values despite compliance with optimal insulin therapy,
- c. Will be prescribed the requested amylin analog in combination with insulin;

AND

- 5. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Hypoglycemics, Incretin Mimetic/Enhancer with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

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 AN AMYLIN ANALOG: Requests for prior authorization of renewals of prescriptions for an amylin analog that were previously approved will take into account whether the beneficiary:

- 1. Has improved glycemic control as evidenced by a recent HbA1c value; AND
- 2. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Hypoglycemics, Incretin Mimetic/Enhancer with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

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. <u>Clinical Review Process</u>

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, Incretin Mimetic/Enhancer. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable 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.



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SYMLIN (pramlintide) PRIOR AUTHORIZATION FORM

Prior authorization guidelines for Hypoglycemics, Incretin Mimetics/Enhancers (including Symlin) and Quantity Limits/Daily Dose Limits are available on the DHS Pharmacy Services website at https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/default.aspx.

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|--|--------------------------------------|--|-------------|--------------------------|----------|---|---|--|--|--|
| □ New request □ Renewal request # 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: | | | | | | | |
| | IFORMATION | | | | | | | | | |
| | | | | | | | | | | |
| Product requested: | SymlinPen 60 pen injector Quantity: | | | ntity: | Refills: | | | | | |
| 4 | SymlinPen 120 pen injector Quantity: | | | | | Refills: | | | | |
| Directions: | | | | | | | | | | |
| Diagnosis (submit documentation): | | | | | | Diagnosis code (<u>required</u>): | | | | |
| INITIAL requests | | | | | | | | | | |
| What is the beneficiary's dia | agnosis? | | П | ype 1 diabetes | | Type 2 diabetes | | | | |
| What is the beneficiary's most recent hemoglobin A1c? HbA1c:% | | | | | | Date of test:// | | | | |
| Has the beneficiary failed to achieve adequate glycemic control while adherent with optimal insulin therapy? | | | | | | □Yes □No | Submit documentation of insulin regimens tried and outcomes, including HbA1c results. | | | |
| Will the beneficiary be using Symlin in addition to insulin? | | | | | | | | | | |
| List insulins that will be used: | | | | | | ☐Yes Submit documentation of current, ☐No complete medication list. | | | | |
| For a diagnosis of type 2 diabetes, does the beneficiary have a history of failure to achieve glycemic control using maximum tolerated doses of metformin or a contraindication or intolerance to metformin? | | | | | | □Yes □No | | | | |
| <u>For a diagnosis of type 2 diabetes</u> , does the beneficiary have a history of failure to achieve glycemic control with the preferred Hypoglycemics , Incretin Mimetics or have a contraindication or intolerance to these medications? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred Hypoglycemics, Incretin Mimetics. | | | | | | □Yes □No | Submit documentation of HbA1c results and/or contraindications or intolerances. | | | |
| RENEWAL requests | | | | | | | | | | |
| Since starting Symlin, did the beneficiary experience improved glycemic control? | | | | | | ☐Yes ☐No | Submit documentation of clinical response. | | | |
| What is the beneficiary's most recent hemoglobin A1c (since Symlin was started or last approved)? HbA1c:% | | | | | | Date of test:// | | | | |
| PLEASE <u>FAX</u> COMPLETED FORM TO GATEWAY – PHARMACY DIVISION | | | | | | | | | | |
| | | | | | | | | | | |
| Prescriber Signature: | | | | | | Date: | | | | |

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HYPOGLYCEMICS, INCRETIN MIMETICS PRIOR AUTHORIZATION FORM

| ☐New request | Renewal request | total # of pgs: | Prescribe | name: | | | | | |
|--|-----------------|-----------------|------------|---|-----------|-------|------------------|----------|--|
| | | | | | | | | | |
| Name of office contact: | | | Specialty: | | | | | | |
| Contact's phone number: | | | | | | | State license #: | | |
| LTC facility contact/phone: | | | | Street address: | | | | | |
| Beneficiary name: | | | Suite #: | Suite #: City/state/zip: | | | | | |
| Beneficiary ID#: | | DOB: | Phone: | | | Fax: | | | |
| | | CLINICAL INF | ORMAT | ION | | | | | |
| Drug requested: | | | | Strength: | | | | | |
| Dose/directions: | | | | | Quantity: | | ty: | Refills: | |
| Diagnosis (<u>submit documentation</u>): | | | | Dx code (<u>required</u>): | | | | | |
| 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, contraindication, or intolerance of maximum tolerated doses of metformin ? | | | | □Yes □No | · | | | | |
| <u>Requests for NON-PREFERRED agents</u> : Does the beneficiary have a history of trial and failure, contraindication, or intolerance of the preferred Hypoglycemics, Incretin Mimetics? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in each class. | | | | Submit all supporting documentation of preferred agents tried and treatment outcomes, including contraindications or intolerances. | | | | | |
| PLEASE <u>FAX</u> COMPLETED FORM TO GATEWAY – PHARMACY DIVISION | | | | | | | | | |
| Prescriber Signature | e: | | | | | Date: | | | |

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HYPOGLYCEMICS, INCRETIN ENHANCERS PRIOR AUTHORIZATION FORM

| ☐New request | Renewal request | total # of pgs: | Prescribe | riber name: | | | | | | |
|---|---|-----------------|------------|---|-------------|------------------|--------|----------|--|--|
| Name of office contact: | | | Specialty: | | | | | | | |
| Contact's phone number: | | | NPI: | | | State license #: | | | | |
| LTC facility contact/phone: | | Street address: | | | | | | | | |
| Beneficiary name: | | | | Suite #: City/stat | | | e/zip: | | | |
| Beneficiary ID#: | | DOB: | Phone: | | | | Fax: | | | |
| | | CLINICAL INI | FORMAT | ION | | | | | | |
| Drug requested: | | | | Strength: | | | | | | |
| Dose/directions: | | | | | Quantity: F | | | Refills: | | |
| Diagnosis (<u>submit documentation</u>): | | | | Dx code (<u>required</u>): | | | | | | |
| 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, contraindication, or intolerance of maximum tolerated doses of metformin ? | | | | Submit documentation showing trial and Yes failure of, or contraindication or intolerance to, metformin (including result of a recent HbA1c). | | | | | | |
| <u>Requests for NON-PREFERRED agents</u> : Does the beneficiary have a history of trial and failure, contraindication, or intolerance of the preferred Hypoglycemics, Incretin Enhancers? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in each class. | | | | Submit all supporting documentation of Yes preferred agents tried and treatment No outcomes, including contraindications or intolerances. | | | | | | |
| | PLEASE <u>FAX</u> COMPLETED FORM TO GATEWAY – PHARMACY DIVISION | | | | | | | | | |
| Prescriber Signature: | | | | | | Date: | | | | |

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