

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Incretin Mimetic/Enhancer Hypoglycemics (formerly referred to as Other Hypoglycemics)

A. Thresholds for Prior Authorization

All prescriptions for Incretin Mimetic/Enhancer Hypoglycemics, both preferred and non-preferred, regardless of the quantity prescribed, must be prior authorized. See Preferred Drug List (PDL) for the list of preferred Incretin Mimetic/Enhancer Hypoglycemics at:

www.providersynergies.com/services/documents/PAM_PDL.pdf

See Quantity Limits for the list of drugs with quantity limits at:

<http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>

B. Review of Documentation for Medical Necessity

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

1. For **Byetta**, whether the recipient:

a. Has a diagnosis of Type 2 Diabetes Mellitus

AND

b. Is 18 years of age or older

AND

c. Has a documented history of:

i. Failure to respond to maximum tolerated doses of metformin in combination with a sulfonylurea or metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value

OR

ii. A contraindication or intolerance to metformin and TZD and sulfonylurea

AND

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- d. Does not have a history of, or is not presenting symptoms of, pancreatitis or gastroparesis

AND

- e. Has CrCl>30mL/min

AND

- f. Does not have a documented history of any other contraindication to Byetta

Note for renewals of prescriptions for Byetta: Requests for prior authorization of renewals of prescriptions for Byetta that were previously approved will take into account whether the recipient:

- a. Has improved glycemic control as evidenced by the recipient's HbA_{1c} value

AND

- b. Does not have a history of, or is not presenting symptoms of, pancreatitis or gastroparesis

AND

- c. Has CrCl>30mL/min

AND

- d. Does not have a documented history of any other contraindication to Byetta

2. For **Symlin**, whether the recipient:

- a. Has a diagnosis of Type 1 Diabetes Mellitus with the following:
 - i. Requires three (3) or more insulin injections daily (using a medically acceptable regimen of insulin that is consistent with current medical standards)

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OR

- ii. Is using an insulin pump

OR

- b. Has a diagnosis of Type 2 Diabetes Mellitus with the following:

- i. A documented history of failure to respond to maximum tolerated doses of metformin in combination with a sulfonylurea as evidenced by the recipient's HbA_{1c} value **OR**
- ii. A documented history of a contraindication or intolerance of metformin and sulfonylurea

AND

- iii. Requires three (3) or more insulin injections daily (using a medically acceptable regimen of insulin that is consistent with current medical standards)

OR

- iv. Is using an insulin pump

AND

- c. Failed to achieve adequate glycemic control despite compliance with individualized insulin management, defined as:

- i. HbA_{1c} level is greater than 7.5% and less than 9%

OR

- ii. Marked day-to-day variability in glucose levels (based on review of self-monitoring blood glucose levels)

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AND

- d. Carries out home blood glucose monitoring three (3) or more times per day

AND

- e. Has no history of recurrent severe hypoglycemia requiring medical intervention during the previous six (6) months

AND

- f. Has no presence of hypoglycemia unawareness

AND

- g. Does not have a diagnosis of gastroparesis

AND

- h. Has no need for medications that stimulate GI motility

AND

- i. Is 18 years of age or older

AND

- j. Is not concurrently using Other Hypoglycemics that have not been approved for use with Symlin

AND

- k. Does not have a documented history of any other contraindication to Symlin

Note for renewals of prescriptions for Symlin: Requests for prior authorization of renewals of Symlin that were previously approved will take into account the following:

- a. Improved glycemc control as evidenced by HbA_{1c} lowering from baseline

AND

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- b. No recurrent, unexplained hypoglycemia that requires medical intervention

AND

- c. No persistent clinically significant nausea or associated abdominal pain

AND

- d. Compliance with self-monitoring of blood glucose concentrations

AND

- e. Does not have a documented history of any other contraindication to Symlin

3. For **Januvia**, whether the recipient:

- a. Has a documented diagnosis of Type 2 Diabetes Mellitus,

AND

- b. Is 18 years of age or older

AND

- c. Has a documented history of:

- i. Failure to achieve glycemic control with maximum tolerated doses of metformin in combination with a sulfonylurea or metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value

OR

- ii. A contraindication or intolerance to metformin and TZD and sulfonylurea,

AND

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- d. If receiving insulin therapy, is using a medically acceptable regimen of insulin that is consistent with current medical standards

AND

- e. Does not have a history of and is not presenting symptoms of pancreatitis

AND

- f. Does not have a documented history of any other contraindication to Januvia

Note for renewals of prescriptions for Januvia: Requests for prior authorization of renewals of Januvia that were previously approved will take into account the following:

- a. Improved glycemic control as evidenced by the recipient's HbA_{1c} value

AND

- b. No history of or presenting symptoms of pancreatitis

AND

- c. No documented history of any other contraindication to Januvia

- 4. For Janumet, whether the recipient:

- a. Has a documented diagnosis of Type 2 Diabetes Mellitus

AND

- b. Is 18 years of age or older

AND

- c. Has a documented history of:
 - i. Failure to achieve glycemic control with maximum tolerated doses of metformin in combination with a sulfonylurea, or

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metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value

OR

- ii. A contraindication or intolerance to a sulfonylurea and a TZD

AND

- d. Does not have a history of and is not presenting symptoms of pancreatitis

AND

- e. Does not have a documented history of any other contraindication to Janumet

Note for renewals of prescriptions for Janumet:

Requests for prior authorization of renewals of Janumet that were previously approved will take into account the following:

- a. Improved glycemic control as evidenced by the Recipient's HbA_{1c} value

AND

- b. No history of and is not presenting symptoms of pancreatitis

AND

- c. No documented history of any other contraindication to Janumet

- 5. For Victoza, whether the recipient:

- a. Has a diagnosis of Type 2 Diabetes Mellitus

AND

- b. Is 18 years of age or older

AND

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c. Has a documented history of:

- i. Failure to respond to maximum tolerated doses of metformin in combination with a sulfonylurea or metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value

OR

- ii. A contraindication or intolerance to metformin and TZD and sulfonylurea

AND

- d. Does not have a history of, or is not presenting symptoms of, pancreatitis or gastroparesis

AND

- e. Does not have a personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

AND

- f. Does not have a documented history of any other contraindication to Victoza

Note for renewals of prescriptions for Victoza: Requests for prior authorization of renewals of prescriptions for Victoza that were previously approved will take into account whether the recipient:

- a. Has improved glycemic control as evidenced by the recipient's HbA_{1c} value

AND

- b. Does not have a history of, or is not presenting symptoms of pancreatitis or gastroparesis

6. For **Onglyza**, whether the recipient:

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- a. Has a documented diagnosis of Type 2 Diabetes Mellitus

AND

- b. Is 18 years of age or older

AND

- c. Has a documented history of:
 - i. Failure to achieve glycemic control with maximum tolerated doses of metformin in combination with a sulfonylurea or metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value

OR

- ii. A contraindication or intolerance to metformin and TZD and sulfonylurea

AND

- d. Does not have a documented history of any contraindication to Onglyza

Note for renewals of prescriptions for Onglyza:

Requests for prior authorization of renewals of Onglyza that were previously approved will take into account the following:

- a. Improved glycemic control as evidenced by the recipient's HbA_{1c} value

AND

- b. No documented history of any other contraindication to Onglyza

7. For **Kombiglyze XR**, whether the recipient:

- a. Has a documented diagnosis of Type 2 Diabetes Mellitus

AND

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- b. Is 18 years of age or older

AND

- c. Has a documented history of:
- i. Failure to achieve glycemic control with maximum tolerated doses of metformin in combination with a sulfonylurea or metformin in combination with a TZD as evidenced by the recipient's HbA_{1c} value
OR
 - ii. A contraindication or intolerance to TZD and sulfonylurea

AND

- d. Does not have a documented history of any contraindication to Kombiglyze XR

Note for renewals of prescriptions for Kombiglyze XR:

Requests for prior authorization of renewals of Kombiglyze XR that were previously approved will take into account the following:

- a. Improved glycemic control as evidenced by the recipient's HbA_{1c} value

AND

- b. No documented history of any other contraindication to Kombiglyze

AND

8. For all non-preferred Incretin Mimetic/Enhancer Hypoglycemics, whether the recipient has a documented history of therapeutic failure, contraindication or intolerance of the preferred Incretin Mimetic/Enhancer Hypoglycemics

OR

9. For all Incretin Mimetic/Enhancer Hypoglycemics, if the request does not meet the clinical review guidelines listed above but in the professional judgment of the physician

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reviewer, the therapy is medically necessary to meet the medical needs of the recipient

10. If a prescription for an Incretin Mimetic/Enhancer Hypoglycemic is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

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 the request for a prescription for an Incretin Mimetic/Enhancer Hypoglycemic. 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 recipient.

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