ALBERTA BLUE CROSS®

# INOTERSEN / PATISIRAN FOR HATTR-PN
## SPECIAL AUTHORIZATION REQUEST FORM

**Patients may or may not meet eligibility requirements as established by Alberta government sponsored drug programs.**

**Please complete all required sections to allow your request to be processed.**

| **PATIENT INFORMATION** | | | | **COVERAGE TYPE** |
|---|---|---|---|---|
| LAST NAME | FIRST NAME | | INITIAL | ☐ Alberta Blue Cross |
| BIRTH DATE (YYYY-MM-DD) | ALBERTA PERSONAL HEALTH NUMBER | | | ☐ Alberta Human Services<br>☐ Other _____ |
| ADDRESS | CITY | PROV | POSTAL CODE | ID/CLIENT/COVERAGE NUMBER |

| **PRESCRIBER INFORMATION** | | | |
|---|---|---|---|
| PRESCRIBER LAST NAME | FIRST NAME | INITIAL | PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION<br>☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other<br>REGISTRATION NUMBER |
| ADDRESS | | | |
| CITY, PROVINCE | | | PHONE / FAX |
| POSTAL CODE | | | FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED |

**Drug requested** ☐ **Inotersen (e.g. Tegsedi)** ☐ **Patisiran (e.g. Onpattro)**

**Please provide the following information for ALL requests**

**Diagnosis**

☐ Hereditary transthyretin amyloidosis polyneuropathy (hATTR-PN)

☐ Other (specify)

_____

**Please indicate if this patient is**

☐ starting drug upon approval ……....complete section I

☐ new to coverage but currently maintained on drug …..complete section I & II

☐ submitting renewal request …….. complete section II

**Combination use**

Please indicate if the patient will be using the requested drug in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR ☐ Yes ☐ No

**Section I: INITIAL requests for treatment naïve and treatment experienced patients**

**Does the patient have a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR)?**

☐ Yes → please provide a copy of the genetic test report ☐ No

**Please indicate if the following apply to this patient at treatment initiation (check all that apply):**

☐ is symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II

☐ does NOT exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)

☐ has NOT previously undergone a liver transplant

**Section II: RENEWAL requests and INITIAL requests for treatment experienced patients**

| **Please indicate if the following currently apply to this patient (check Yes or No for a-c below):** | **Yes** | **No** |
|---|---|---|
| a) shows continued benefit from treatment with the requested drug | ☐ | ☐ |
| b) is permanently bedridden and dependent on assistance for basic activities of daily living | ☐ | ☐ |
| c) is receiving end-of-life care | ☐ | ☐ |

**Additional information relating to request**

| PRESCRIBER'S SIGNATURE | DATE (YYYY-MM-DD) | Please forward this request to<br>**Alberta Blue Cross, Clinical Drug Services**<br>**10009 108 Street NW, Edmonton, Alberta T5J 3C5**<br>FAX **780-498-8384** in Edmonton • **1-877-828-4106** toll free all other areas |
|---|---|---|

**ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE FAX YOUR REQUEST.**

# INOTERSEN / PATISIRAN FOR HATTR-PN
## SPECIAL AUTHORIZATION CRITERIA

**Patients may or may not meet eligibility requirements as established by Alberta government sponsored drug programs.**

**Criteria for coverage**

### INOTERSEN (e.g. Tegsedi) special authorization criteria

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:
- Are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved for 284 mg administered subcutaneously once weekly for a period of nine months. Patients will be limited to receiving a four-week supply of inotersen per prescription at their pharmacy.

For renewal of coverage, patients must show continued benefit from treatment with inotersen and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.
Continued coverage may be approved for 284 mg weekly for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."

### PATISIRAN (e.g. Onpattro) special authorization criteria

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:
-Patients are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved 30 mg administered intravenously once every three weeks for a period of nine months. Patients will be limited to receiving one dose of patisiran per prescription at their pharmacy.

For renewal of coverage, patients must show continued benefit from treatment with patisiran and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.
Continued coverage may be approved for 30 mg every three weeks for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."


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