Respiratory Syncytial Virus (RSV) Prophylaxis for High-Risk Infants Program

Enrolment and Drug Ordering Processes for the 2018-2019 Season

Enrolment Form

- To protect personal health information, **NO** personal health identifiers (e.g. name, address, health card number, parent names) are to be provided on the enrolment form. Fields for the infant’s full name and health card number and other personal identifiers have been removed.
- The following table outlines changes to the enrolment form for the upcoming season:

<table>
<thead>
<tr>
<th>Applicable Section of Form</th>
<th>Change to the enrolment form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1</td>
<td>Addition of ‘Gestational age at birth’ field</td>
</tr>
<tr>
<td>Section 5</td>
<td>Addition of diagnoses ‘Single Ventricle’ and ‘Cardiomyopathy’ fields, with an additional ‘Other’ field to provide further conditions</td>
</tr>
</tbody>
</table>

**Special Clinical Circumstance Medical Justification Form**

- The Special Clinical Circumstance Medical Justification Form (Medical Justification Form) has been developed to facilitate submission of enrolment requests for high-risk infants who do not satisfy the enrolment criteria for approval. This form must be completed and should accompany enrolment requests submitted for Consideration of Special Clinical Circumstances.
The following table outlines changes to the special clinical circumstance medical justification form for the upcoming season:

<table>
<thead>
<tr>
<th>Applicable Section of Form</th>
<th>Change to the medical justification form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2</td>
<td>An additional section was added to determine if a specialist consultation was sought and the results of the consultation. A reminder was added to attach any further documentation or additional information to the form, such as a letter of support from a specialist, if available.</td>
</tr>
</tbody>
</table>

Links to the enrolment form and Medical Justification Form are available from the RSV Prophylaxis for High-Risk Infants Program (Program) webpage.

**Enrolment Process**

- All enrolments will initially be processed by the Synagis Coordinator at AbbVie Canada (Synagis Coordinator).
- All enrolment forms and Medical Justification Forms (if applicable) should be faxed to the Synagis Coordinator at 1-888-703-6967. **To protect personal health information, NO personal health identifiers (e.g. name, address, health card number, parent names) are to be provided on the forms or any supporting documents.**
- The RSV season reference number will be provided by the Synagis Coordinator if the enrolment request is approved.
- The ministry’s RSV Prophylaxis Program coordinator will review enrolment requests for the BPD/CLD and CHD criteria and have requests submitted under Special Clinical Circumstances reviewed by external medical experts in RSV prophylaxis. The ministry’s medical experts may directly contact the enrolling physician for additional information if necessary.
- The turn-around time is one business day for most requests. For requests submitted under the BPD/CLD or CHD criteria and the Consideration of Special Clinical Circumstances category, the average turn-around time is three business days.
Drug Ordering Process

- All shipment orders for palivizumab will be directed to the Synagis Coordinator (fax: 1-888-703-6967). The Synagis® Order Form is available from the Program’s webpage or by calling the Synagis Coordinator at 1-888-704-8270.
- The first dose can be ordered in Section 7 of the enrolment form and will be shipped upon approval of enrolment. All subsequent shipments should be ordered on the Synagis® Order Form.
- The first dose and all subsequent doses can be ordered on the Synagis® Order Form if a shipment of the first dose is not required at time of enrolment request.
- If there are any vials left over from last season, please use those vials prior to ordering another shipment of palivizumab.
- During mid-season (mid-January), the ministry asks that you take note of the number of vials of palivizumab in your inventory and take this into account when ordering another shipment of palivizumab for the remainder of the season. The intent is to reduce inventory to zero by season end.
- Except for orders placed on Fridays, weekends and statutory holidays, shipments generally occur within 24 hours. However, it is recommended that an order be placed five business days prior to the infant’s date of injection to avoid any unforeseen circumstances.
- Please note that the first shipment of palivizumab vials from the manufacturer will be on or after Monday, November 5th, 2018.
- To maintain cold chain, palivizumab must be stored in refrigerated conditions between 2 and 8°C in its original container. Please ensure that the drug is stored properly upon receipt.

Dosing Schedule

- Ontario’s RSV Advisory Group recommends palivizumab be administered according to the following general dosing schedule for central and southern Ontario:
  - Dose number 1 (week number 0) to be given starting the week of November 19th
  - Dose number 2 (week number 3) to be given in the month of December
  - Dose number 3 (week number 7) to be given in the month of January
  - Dose number 4 (week number 11) to be given in the month of February
  - Dose number 5 (week number 15) to be given in the month of March
- The season and prophylaxis start date for northern Ontario is generally delayed in comparison to southern Ontario and consequently, the suggested dosing schedule should be adjusted accordingly.
• The second dose should be given 21-28 days after the initial dose. The third and subsequent doses should be administered every 28-35 days.
• Up to a maximum of 5 doses will be funded by the Program. A sixth dose will NOT be covered by the Program, except in isolated circumstances which will require approval by the ministry. Should a sixth dose be required, contact the ministry at RSVProphylaxisProgram@ontario.ca.

Please refer to the Program’s webpage for links to the guidelines, general information, answers to frequently asked questions and applicable forms for the current RSV prophylaxis season.