Positive Quality Intervention: Ruxolitinib (Jakafi®) - Managing Myelofibrosis Patients

Description of PQI: Ruxolitinib is a selective Jak2 inhibitor used for the treatment of myelofibrosis (MF). This PQI will review the close monitoring of platelets required to ensure appropriate dose and avoid severe thrombocytopenia due to the therapy.

Background: Ruxolitinib is FDA approved for the treatment of intermediate or high-risk patients with MF. This includes patients with primary MF, post polycythemia vera MF, and post-essential thrombocytopenia MF.

PQI Process: Pharmacy management of patients’ labs to ensure correct dosing of ruxolitinib can contribute to increased efficacy and decreased toxicity of the therapy. When receiving a new prescription for ruxolitinib:

- Review dosing
  - Dosing is based on baseline platelet count and platelet counts must be monitored throughout therapy

<table>
<thead>
<tr>
<th>Baseline Platelet Count</th>
<th>Ruxolitinib Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;200 x 10⁹ cells/L</td>
<td>20 mg BID</td>
</tr>
<tr>
<td>100 to 200 x 10⁹ cells/L</td>
<td>15 mg BID</td>
</tr>
<tr>
<td>50 to 99 x 10⁹ cells/L</td>
<td>5 mg BID</td>
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</tbody>
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- Check for drug-drug interactions
- Lab Monitoring
  - CBC/CMP - baseline, every 2 to 4 weeks until dose is stabilized, then as clinically indicated
  - Lipid panel - Baseline and 8 to 12 weeks after initiation
- Ensure the patient has follow up labs scheduled appropriately (see lab monitoring section)
  - Add reminders in pharmacy management software or EMR for follow-up on patient’s labs every 2-4 weeks until dose is stabilized (usually within 8 weeks)
- Refills will be filled only after:
  - CBC has been checked
  - Platelet count has been evaluated for appropriateness of dose
- Dose Modifications:
  - Do not adjust dose within the first 4 weeks, and no more than every 2 weeks thereafter
  - Dose may be increased by 5 mg BID increments to a max dose of 25 mg BID if:
    - Failure to achieve a reduction from baseline spleen length of 50% or a 35% reduction in spleen volume as measured by CT or MRI
    - Platelet count more than 125 x 10⁹ cells/L at treatment week 4 and platelet counts never less than 100 x 10⁹ cells/L
    - ANC more than 0.75 x 10⁹ cells/L

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PQI Process Continued:

- Discontinue ruxolitinib if spleen size reduction or symptom improvements not observed after 6 months of therapy
- When discontinuing therapy for any reason other than thrombocytopenia, consider gradually tapering dose by 5 mg twice daily each week

- Evaluate platelet count and may recommend the following dose adjustments to provider:

Baseline Platelet Count of 100 x 10(9) cells/L or Higher: ¹

<table>
<thead>
<tr>
<th>Current Platelet Count</th>
<th>Dose Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>125 x 10^9 cells/L or higher</td>
<td>No dose adjustment</td>
</tr>
</tbody>
</table>
| 100 to 124 x 10^9 cells/L | If starting dose was 20 mg BID, decrease dose by 5 mg BID  
                          | If starting dose was 15 mg BID or less, no adjustment needed |
| 75 to 99 x 10^9 cells/L | Decrease dose to 10 mg BID  
                          | If starting dose was 10 mg BID or less, no adjustment needed |
| 50 to 74 x 10^9 cells/L | Decrease to 5 mg BID  
                          | If starting dose was 5 mg BID, no adjustment needed |
| <50 x 10^9 cells/L | Hold. May restart when platelets >50 x 10^9 cells/L |

Baseline Platelet Count of 50 to 99 x 10^9 cells/L: ¹

<table>
<thead>
<tr>
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<th>Dose Adjustment</th>
</tr>
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</table>
| 25 to 35 x 10^9 cells/L and platelet decline during prior 4 weeks is less than 20% | Decrease total daily dose by 5 mg.  
                          | For patients on 5mg once daily prior to decline, continue same dose |
| 25 to 35 x 10^9 and platelet decline during prior 4 weeks is 20% or higher | Decrease dose to 5mg BID  
                          | If dose is 5 mg BID, decrease to 5 mg once daily  
                          | If dose is 5 mg once daily, continue same dose |
| <25 x 10^9 | Hold therapy  
                          | May restart when platelets >35 x 10^9 cells/L starting with 5 mg BID less than previous dose |

Patient Centered Activities:

- Provide Oral Chemotherapy Education (OCE) sheet
- Stress importance of adherence
  - The only way to achieve the proper patient-specific dose is if the patient is adherent
  - Schedule follow-up calls
- Provide education:

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**Patient Centered Activities Continued:**

- Laboratory monitoring
- Possibility of dose adjustments based on labs
  - Monitoring Skin:
    - Important to note all skin lesions
      - Examine skin at baseline
      - Make note of any new lesions that arise while on therapy

**References:**