National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

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Positive Quality Intervention: Managing Myelofibrosis Patients

Description of PQI: Jakafi (ruxolitinib) is a selective Jak2 inhibitor used for the treatment of myelofibrosis (MF). It is a drug that requires close monitoring of platelets to ensure that a patient is on the appropriate dose and avoids 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 myelofibrosis, post PV MF, and post ET myelofibrosis. A retrospective study of 108 patients (25 of which had low risk MF) showed patients who had moderate or severe splenomegaly reduced from 64% to 16% and moderate or severe fatigue reduced from 90% to 37% from diagnosis to time to best response with ruxolitinib. This led to a category 2A recommendation in patients with low-risk, symptomatic MF.

Dosing of Ruxolitinib is based on baseline platelet count and platelet counts need to be monitored throughout therapy.

Baseline dosing of ruxolitinib is as follows*:

Platelet Count	Ruxolitinib Dose
>200 x 10(9) cells/L	20 mg BID
100 to 200 x 10(9) cells/L	15 mg BID
50 to 99 x 10(9) cells/L	5mg BID

*Always assess pertinent drug-drug interactions and adjust dose accordingly

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 a new prescription for ruxolitinib is sent to the pharmacy, the pharmacist will:

Ensure that the patient has had a CBC, CMP, and lipid panel taken at baseline
Ensure that the initial prescription is dosed properly
Ensure the patient has follow up labs scheduled appropriately (discussed later)
Counsel on ruxolitinib
Add reminder in pharmacy management software for follow up on patient's labs every 2-4 weeks until dose is stabilized (usually within 8 weeks).

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Refills will be filled only after:

CBC has been checked
Platelet count has been evaluated for appropriateness of dose

Pharmacy will evaluate platelet count and dose and recommend the following dose adjustments to the prescribing physician.

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

Current Platelet Count	Dose Adjustment
125 x 10(9) cells/L or higher	No dose adjustment
100 to 124 x 10(9) cells/L	If starting dose was 20mg BID, decrease dose by 5mg BID. If starting dose was 15mg BID or less, no adjustment needed
75 to 99 x 10(9) cells/L	Decrease dose to 10mg BID If starting dose was 10mg BID or less, no adjustment needed
50 to 74 x 10(9) cells/L	Decrease to 5mg BID If starting dose was 5mg 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:

Current Platelet Count	Dose Adjustment
25 to 35 x 10(9) cells/L and platelet decline during prior 4 weeks is less than 20%	Decrease total daily dose by 5mg. 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 5mg BID, decrease to 5mg once daily If dose is 5mg once daily, continue same dose
<25 x 10(9)	Hold therapy. May restart when platelets >35 x 10(9) cells/L starting with 5mg BID less than previous dose

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Dose Modifications:

- Dose adjust as noted above
- Do not adjust dose within the first 4 weeks, and no more than every 2 weeks thereafter
- Dose may be increased by 5mg BID increments to a max dose of 25mg BID if the patient meets the following:
    - 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 109cells/L.
- Discontinue ruxolitinib if spleen size reduction or symptom improvement is 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

Lab Monitoring:

- CBC - baseline, every 2 to 4 weeks until dose is stabilized, then as clinically indicated
- Lipid panel - Baseline and 8 to 12 weeks after initiation
- Renal and hepatic function

Patient Centered Activities:

- Stress importance of adherence
    - The only way to achieve the proper patient-specific dose is if the patient is adherent to therapy
    - Schedule follow up calls
- Provide education:
    - Laboratory monitoring
    - Possibility of dose adjustments based on labs
- Monitoring Skin:
    - Important to notice all skin lesions
        - Examine skin at baseline
        - Make note of any new lesions that arise while on therapy