





Switching Between Therapies in Polycythemia Vera

RECOMMENDED SHIFT

Patients with polycythaemia vera who are receiving hydroxyurea are recommended to change to another cytoreductive drug if they meet at least one of the following criteria:

Inefficacy

 Development of vascular events: either clinically relevant bleeding, venous thrombosis, or arterial thrombosis (consensus: 80%; strength of the recommendation: weak)

Intolerance

- Intolerance to hydroxyurea because of grade 3–4 or prolonged grade 2 non-haematological toxicity (eg, mucocutaneous manifestations, gastrointestinal symptoms, fever, or pneumonitis) at any dose (consensus: 100%; strength of the recommendation: strong. Note that the expert panel provided a strong recommendation if it was confident that the desirable effects of adherence to the recommendation outweigh the undesirable effects)
- Intolerance to hydroxyurea because of haematological toxicity (haemoglobin <100 g/L, platelet count <100 x 10° cells per L, or neutrophil count <1 x 10° cells per L) at the lowest dose of hydroxyurea to achieve a response⁵³ (consensus: 100%; strength of the recommendation: strong)
- Development of non-melanoma skin cancers (consensus: 80%; strength of the recommendation: weak)



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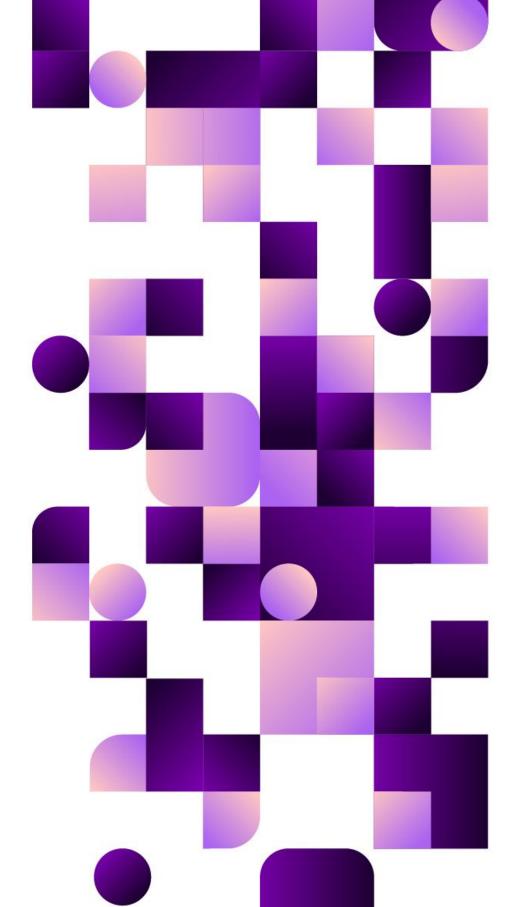
SHIFT to be CONSIDERED

Patients with polycythaemia who receive hydroxyurea should be considered to change to another cytoreductive drug if they show an insufficient clinical response to hydroxyurea (at ≥1.5 g per day for at least 4 months and without reporting intolerance), as defined by at least one of the following criteria:

Inefficacy

- Persistent disease-related symptoms: a total symptom score
 of at least 20 or an itching score of at least ten for at least
 6 months (consensus: 92%; strength of the
 recommendation: strong)
- Persistent thrombocytosis: a platelet count >1000 × 10° cells per L, microvascular symptoms, or both, persisting for more than 3 months (consensus: 92%; strength of the recommendation: weak)
- Symptomatic or progressive splenomegaly: increased in spleen size by more than 5 cm from the left costal margin in 1 year (consensus: 83%; strength of the recommendation: weak)
- Progressive (at least 100% increase if baseline count is <10×10° cells per L or at least 50% increase if baseline count is >10×10° cells per L) and persistent leukocytosis (leukocyte count >15×10° cells per L confirmed at 3 months; consensus: 75%; strength of the recommendation: weak)
- Insufficient haematocrit control: need for six or more phlebotomies per year to keep haematocrit below 45% (consensus: 83%; strength of the recommendation: weak)





Il presente documento è il prodotto finale del progetto Clinical Assessment of resistance and Intolerance to Hydroxyurea as Criteria for Second-line Treatment in patients with Polycythemia Vera, condotto nel corso del 2023 e 2024 dal Working Party GIMEMA sulle Neoplasie Mieloproliferative Croniche.

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