Orphan drugs with ≥2 indications are now vulnerable to Medicare price negotiation: Is indication expansion worth the risk?

EE274

William Derrickson, Lilia Leybova, Neha Soni, and Eve Jamali

Global Pricing, Market Access and Analytics, PRECISIONAdvisors

For further information, contact Eve.Jamali@precisionvh.com or visit us on https://www.precisionadvisors.com

Introduction

Orphan drugs with one indication are exempt from price negotiation under the Inflation Reduction Act (IRA), while those with ≥2 indications may be selected for negotiation. This raises questions for manufacturers: Can the expected revenue gain from adding a second indication be negated by IRA price negotiations? And if so, can this be circumvented for oncology agents by pursuing inclusion in NCCN guidelines but **not** FDA approval?

Methods

Jakafi and Imbruvica are two orphan oncology products that pursued indication expansions and are on the Medicare Top 50 Spend List. We developed a model that compares two illustrative cases for each drug. Both situations assume 1.) eligibility for Medicare price negotiation at year 9 post initial FDA approval (per IRA policy); 2.) maximum discounts (per IRA policy), resulting in WAC dropping to 60% of the original price

Case A: FDA approval for both indications, NCCN recommendation for both indications, and application of IRA price negotiations

Case B: FDA approval for the first indication only, NCCN recommendation for both indications, and no adjustment to price

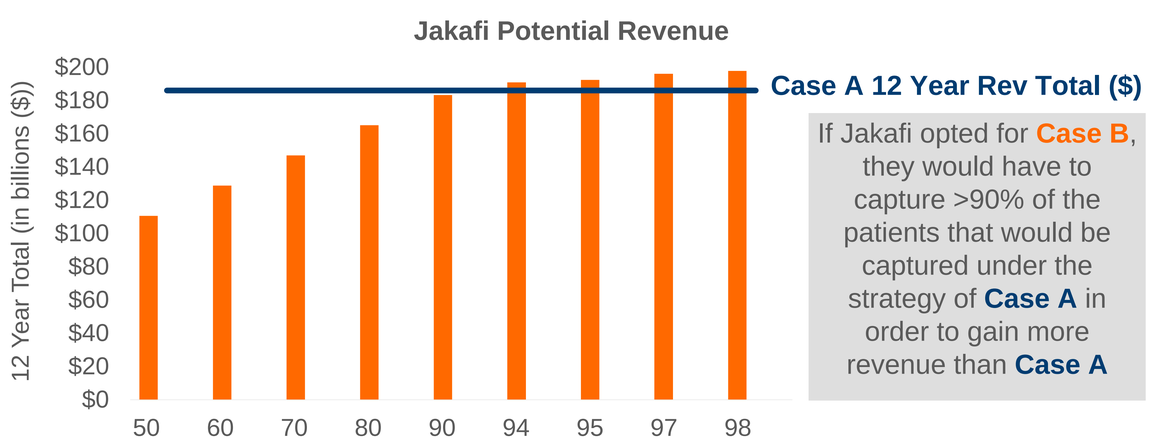
Results

Jakafi

Jakafi launched in 2011 in myelofibrosis (MF) before expanding to polycythemia vera (PV) in 2014. We assume that ~60% of patients with these conditions are covered by Medicare.

Case A: FDA approval for MF & PV, NCCN recommendation for MF & PV, subject to price negotiation

Case B: FDA approval for MF only, NCCN recommendation for MF & PV, no WAC discount



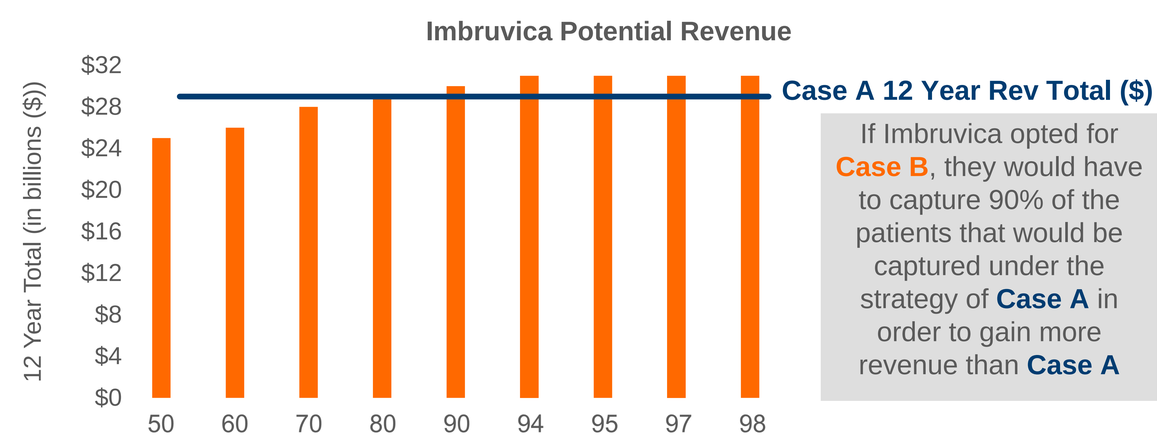
If Jakafi opted for **Case B**, they would have to capture >90% of the patients that would be captured under the strategy of **Case A** in order to gain more revenue than **Case A**

Imbruvica

Imbruvica launched in 2013 in Mantle Cell Lymphoma (MCL) before expanding to Small Lymphocytic Lymphoma (SLL) in 2014. We assume that ~65% of these patients are covered by Medicare.

Case A: FDA approval for MCL & SLL, NCCN rec. for MCL & SLL, subject to price negotiation

Case B: FDA approval for MCL only, NCCN rec. for MCL & SLL, no WAC discount



If Imbruvica opted for **Case B**, they would have to capture 90% of the patients that would be captured under the strategy of **Case A** in order to gain more revenue than **Case A**

Conclusions

The potential for a drug to lose 40% of its WAC price in Medicare initially looks like an outcome to avoid. However, several factors attenuate the impact of IRA negotiated price, most significantly the delay of the discount to 9 years post launch. As well, Medicare coverage and prices only apply to a portion of the patient population for most drugs. The drugs selected for this exercise are likely to have relatively high proportions of Medicare patients, but the benefit gained from avoiding IRA price negotiations was minimal. FDA approval facilitates broader uptake, and launch at a high price point (common in orphan and oncology spaces) can attenuate the net impact of IRA discounting on total lifespan revenue. In sum, this model suggests that pursuing alternative paths to market for orphan drugs vulnerable to IRA price negotiations does not generate a compelling return

PRECISIONadvisors