



**compass
oncology**
THE NORTHWEST CANCER SPECIALISTS

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Dear Kathy and Andrew

Thank you for your comprehensive review of the white blood cell growth factors (WB CGF).

Please see below comments that we hope you will consider at the pharmacy and therapeutics committee review:

A. Agreement with the National Comprehensive Cancer Network (NCCN) guidelines:

NCCN is a good standard/benchmark to follow for selection of WBC GF, however we find in clinical practice there are many patients in whom neutropenia is a risk to avoid. Most clinical trials with WBC GF utilize a primary endpoint of reduction of risk of neutropenic fever.

It is difficult to predict an individual patient's likelihood of neutropenic fever. While the inherent risk of neutropenic fever with a specified regimen (from published clinical trials); is helpful; individual patient and clinical risks for neutropenia and neutropenic fever should also be considered in deciding if a WBC GF is to be used. Some examples of clinical risk factors are listed in NCCN and other resources. In addition, psychosocial factors need to be included in deciding to use a WBC GF. Examples could include: lifestyle, work conditions, living arrangements; and planning vacations. Use of a WBC GF in some situations may allow a patient to remain well, to work, be unburdened of need of additional medical care and assist with maintaining quality of life while receiving cancer treatment.

Thus it is possible that deviation from strict adherence to the NCCN guidelines for use of WBC GF might show up in a Drug Use Evaluation study (DUE), but such would likely be for reasons that can be clinically substantiated.

B. Equivalence of all WBC GF

While there are few head to head studies of the various WBC GF agents, in most situations, these can be considered equivalent for reduction of neutropenic fever. Barriers to use of one agent is best not contingent on failing/intolerance to another agent. Equal access to all agents is preferred, allowing the provider to select the most appropriate agent and site of administration. The cost of these agents is acknowledged, in the event a patient requires additional medical care for infection, these costs quickly outweigh the cost of the WBC GF.

C. Patient Self Injection.

1. Recently the FDA approved tbo filgrastim for self injection:

12/24/2014:- from tbo-filgrastim prescribing information:

"2.2 General Considerations for Administration

GRANIX may be administered by either a healthcare professional or by a patient or caregiver. Before a decision is made to allow GRANIX to be administered by a patient or caregiver, ensure that the patient is an appropriate candidate for self-administration or administration by a caregiver. Proper training on storage, preparation, and administration technique should be provided. If a patient or caregiver is not an appropriate candidate for any reason, then in such patients, GRANIX should be administered by a healthcare professional.

Dispense only the pre-filled syringe without a safety needle guard device to patient or caregiver. Instruct patients and caregivers to follow the Instructions for Use provided with the GRANIX pre-filled syringe to properly administer an injection after training by a healthcare professional"

2. Self-injection of white blood cell factors is often not appropriate for patients. Oncology patients receiving chemotherapy regimens where primary or secondary prophylaxis use of WBC GF are at risk of not completing the prescribed course of white blood cell growth factors if left to do at home/self inject. This may be for various reasons such as not feeling well, not understanding the necessity of the treatment. Such action may increase the likelihood of neutropenic fever.
3. If patients are prescribed daily injection of WBC GF, they need come to the clinic on multiple days. This interferes with their quality of life, takes them away from the safety of their own home, and potentially exposes them to increased risk of infection. In addition, patients may not feel well following therapy, and adding more visits to their schedule is a deterrent to their compliance. In the event, they do not show for an appointment, the provider is challenged with follow up to ensure the patient understands the risks to their health, and making decisions about ongoing use of these

agents. In addition, caregivers may need to take more away time from their usual activities, including work to bring the patient to the clinic.

4. For the reasons stated in 2 and 3, pegfilgrastim is often the preferred agent for WBC GF support. In clinic administration on one day ensures the patient receives the prescribed agent, vs needing multiple injections. It also allows the patient to remain away from the clinic so maintaining quality of life.

Thank you for consideration of these items.

Regards



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Public Comment
Proposed Harvoni™ Guidelines

OSU Drug Use Research and Management Program
Oregon Drug Use Review / Pharmacy & Therapeutics Committee
January 29, 2015

The Caring Ambassadors Program is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written comment on the proposed criteria and suggested revision to the current Hepatitis C PDL class on Harvoni™ for treatment of Chronic Hepatitis C Virus (HCV).

Your proposed guideline will cause Oregonians to develop cirrhosis of the liver, adding another, separate disease to the virus already impacting these patients lives. We respectfully urge you to reconsider criterion 6 of your guideline to include patients with F2 fibrosis scores in addition to those with F3 and F4. Fibrosis staging is imperfect and can often be mischaracterized by one level. As such, a significant number of patients classified as F2 may actually be F3. In addition, many patients with F2 fibrosis will progress to F3 without treatment and, as with most ailments, early treatment is more effective than waiting to treat until additional complications like cirrhosis to develop.

A cirrhotic liver fails to perform the normal functions of the liver, which leads to liver failure. Cirrhotic livers are more prone to become cancerous and liver failure leads to serious complications, even death. HCV is reported to be the leading cause of chronic hepatitis, cirrhosis, and liver cancer and is a primary indication for liver transplant in the western world. [Rosen 2011] “The morbidity and mortality associated with chronic HCV are mainly attributable to its progression toward cirrhosis and hepatocellular carcinoma (HCC).” [Rauch 2010]

By limiting the use of potent HCV treatments to those who have already developed significant liver damage, you are exposing Oregonians with cirrhosis to an individual risk of developing HCC at 1-6% per year. [Sangiovanni Gastroenterology 2004]. These patients will require costly liver cancer imaging tests every 6 months for the rest of their lives. You must not be shortsighted, but consider all of the downstream fiscal and societal costs when looking at this disease and how to treat it.

Criterion 5 of your guideline requires that medication be prescribed by or in consultation with a hepatologist or gastroenterologist—this is an unnecessary additional hurdle for patients seeking treatment and further discriminates against those who cannot access this type of specialist. Further, this strict requirement is not in line with the community standard. Infectious disease specialists have successfully treated viral hepatitis for years with therapies that were more complex and had much

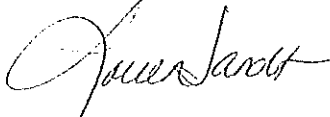
more difficult side effects. It is already a long wait list to see a hepatologist or a gastroenterologist, how can a handful of these doctors also handle consulting on all the cases?

Criterion 10 of your guideline disallows treatment for patients who use drugs and alcohol—there is no substantiated reason for this exclusion and adopting it will bar many of the patients most in need of treatment from being cured of their virus. This exclusion is not in line with the guidelines of the American Association for the Study of Liver Disease (AASLD), which has disseminated the most thorough and widely adopted HCV treatment recommendations in the US. Moreover, large health insurance carriers, such as Aetna, have no mention of excluding drug or alcohol users in their own strict drug plans. If this criterion is adopted, the State of Oregon will again be guilty of discriminating against its own citizens.

Finally, please remove Boceprevir from the PDL list since this is being removed from the US market.

Hepatitis C has a significant impact on quality of life. A recent cohort analysis of 528 HCV infected patients with cirrhosis found baseline health-related quality of life (HRQOL) was significantly impaired, with the most profound impairments in physical activity, energy, vitality, and fatigue. [Younossi, 2014] This impact alone should provide enough reason to treat as many Oregonians as possible as soon as possible. Moreover, letting HCV go untreated leads to issues beyond quality of life; to life itself. Hepatitis C is not only the most prevalent bloodborne viral disease in the US and the largest infectious disease outbreak in our life time, but also the deadliest. [Edlin, Nature 2010] HCV is potentially curable with antiviral therapy, but only a minority of patients have been diagnosed and, of those, fewer than 20% have been offered treatment due to of the difficult side effects of interferon-containing regimens. With new treatments like Harvoni now available, we have a chance to halt this disease in its tracks, but not if we to discriminate against people accessing the Oregon Health Plan. Denying treatment to Oregonians who can be cured of their virus and creating a new population of patients with cirrhosis is both a costly and a deadly path for all concerned.

Thank you for your time and consideration.



Lorren Sandt
Executive Director
Caring Ambassadors Program