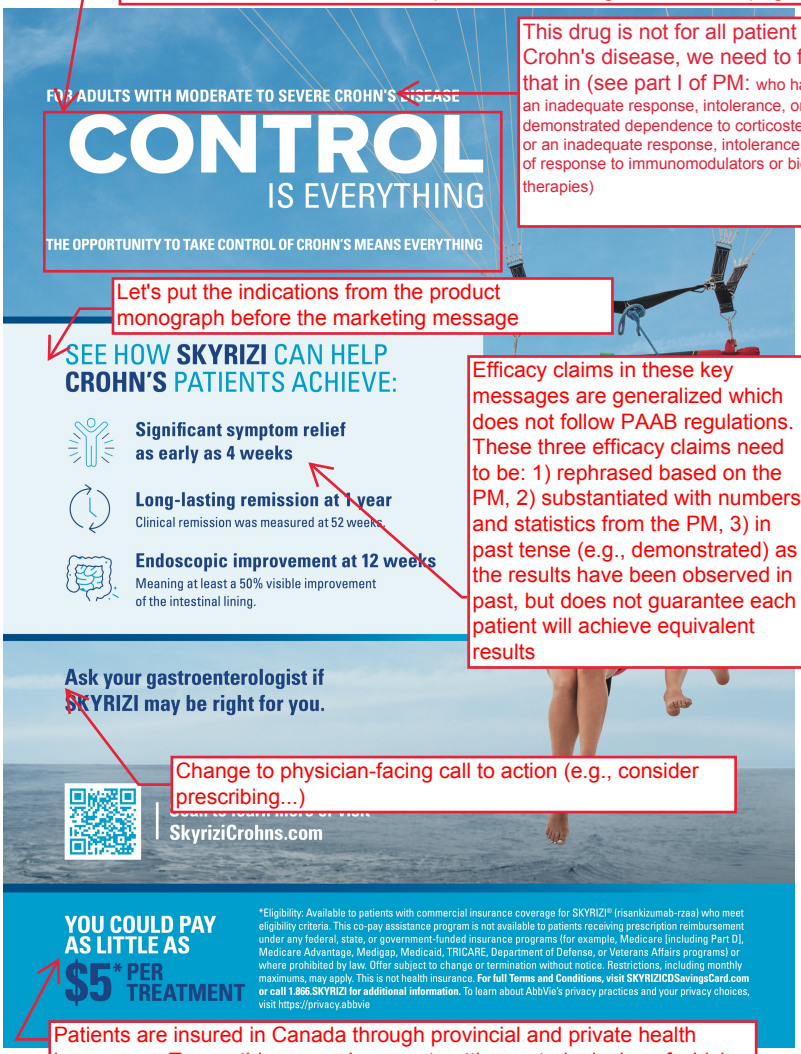
Overall comment: Based on the CTA and safety information, this journal ad seems to be a patient-facing ad. In Canada, branded patient-facing materials are not allowed. We cannot talk about efficacy data to patients or consumers.
To localize this ad in Canada, I am assuming client briefed this ad to be HCP-facing. Hence, all my comments below will be geared to that direction.

The right half of the page currently is the 'medication guide' part from the USPI, almost word-to-word. For Canadian physicians, I suggest to: 1) put the highest-level fair balance (Indications and clinical use, contraindications, most serious warnings and precautions, other relevant warnings and precautions, for more information), 2) change available packaging info, 3) change the reference to product monograph, 4) remove the 'negative side effects reporting' part as we are not writing for patient here.

PAAB may not approve absolute claim like this. Even though it does not say Skyrizi helps to take that absolute control, the presence of the logo in the same page will connote that

I would put **highest-level** fair balance because the major efficacy messages in the left half needs to be balanced with detailed safety information



This drug is not for all patient with Crohn's disease, we need to factor that in (see part I of PM: who have had an inadequate response, intolerance, or demonstrated dependence to corticosteroids; or an inadequate response, intolerance, or loss of response to immunomodulators or biologic therapies)

Let's put the indications from the product monograph before the marketing message

Efficacy claims in these key messages are generalized which does not follow PAAB regulations. These three efficacy claims need to be: 1) rephrased based on the PM, 2) substantiated with numbers and statistics from the PM, 3) in past tense (e.g., demonstrated) as the results have been observed in past, but does not guarantee each patient will achieve equivalent results

Change to physician-facing call to action (e.g., consider prescribing...)

Patients are insured in Canada through provincial and private health insurances. To use this space, I suggest putting a study design of which we mentioned efficacy results in the key messages.

E AND IMPORTANT SAFETY INFORMATION

YRIZI USE[1]

RIZI is a prescription medicine used to treat moderate to re Crohn's disease in adults.

PORTANT SAFETY INFORMATION[1]

t is the most important information I should know ut SKYRIZI® (risankizumab-rzaa)?

RIZI is a prescription medicine that may cause serious effects, including:

Serious allergic reactions:

- Stop using SKYRIZI and get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue, or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching

Infections:

SKYRIZI may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with SKYRIZI and may treat you for TB before you begin treatment with SKYRIZI if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with SKYRIZI.

- Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:
  - fever, sweats, or chills
  - cough
  - shortness of breath
  - blood in your mucus (phlegm)
  - muscle aches
  - warm, red, or painful skin or sores on your body different from your psoriasis
  - weight loss
  - diarrhea or stomach pain
  - burning when you urinate or urinating more often than normal

Do not use SKYRIZI if you are allergic to risankizumab-rzaa or any of the ingredients in SKYRIZI. See the Medication Guide or Consumer Brief Summary for a complete list of ingredients.

Before using SKYRIZI, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **"What is the most important information I should know about SKYRIZI?"**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). Medicines that interact with the immune system may increase your risk of getting an infection after receiving live vaccines. You should avoid receiving live vaccines right before, during, or right after treatment with SKYRIZI. Tell your healthcare provider that you are taking SKYRIZI before receiving a vaccine.
- are pregnant or plan to become pregnant. It is not known if SKYRIZI can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SKYRIZI passes into your breast milk.
- become pregnant while taking SKYRIZI. You are encouraged to enroll in the Pregnancy Registry, which is used to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-877-302-2161 to enroll in this registry.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of SKYRIZI?

SKYRIZI may cause serious side effects. See "What is the most important information I should know about SKYRIZI?"

Liver problems in Crohn's disease: A person with Crohn's disease who received SKYRIZI through a vein in the arm developed changes in liver blood tests with a rash that led to hospitalization. Your healthcare provider will do blood tests to check your liver before, during, and up to 12 weeks of treatment and may stop treatment with SKYRIZI if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms: unexplained rash, nausea, vomiting, stomach (abdominal) pain, tiredness (fatigue), loss of appetite, yellowing of the skin and eyes (jaundice), and dark urine.

The most common side effects of SKYRIZI in people treated for Crohn's disease include: upper respiratory infections, headache, joint pain, stomach (abdominal) pain, injection site reactions, low red blood cells (anemia), fever, back pain, and urinary tract infection.

These are not all the possible side effects of SKYRIZI. Call your doctor for medical advice about side effects.

Use SKYRIZI exactly as your healthcare provider tells you to use it.

SKYRIZI is available in a 600 mg/10 mL vial for intravenous infusion and a 180 mg/1.2 mL or 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit www.AbbVie.com/myAbbVieAssist to learn more.

Reference: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.

180 mg/L not available in Canada

Please see the brief summary of the full Prescribing Information on the following pages and discuss with your doctor.

abbvie

Skyrizi® risankizumab-rzaa

Product Monograph

remove the 'negative side effects reporting' part as we are not writing for patient here.