Michigan state law requires insured health plans to cover off-label use of anti-neoplastics (including adjunctive and supportive drugs) and related reasonable administration costs when supported by the medical literature and recognized oncology organizations generally accept the treatment.


If you enroll participants from self-funded health plans, the health plan may not cover these drugs because they will be excluded as experimental or investigational. You should obtain prior authorization from the health plan if you have any concerns about coverage.

If you are enrolling any Medicare subjects, please consult the Unlabeled Use for Anti-Cancer Drugs MEDICARE form. Medicare has other requirements for the use of off-label drugs, but since most pediatric patients are not covered by Medicare this will generally not be applicable.

If an anti-neoplastic (including adjunctive and supportive drugs) is being used off-label, please consult the following for support: (1) current medical literature substantiates the efficacy of this drug for this type of cancer and (2) recognized oncology organizations generally accept the treatment.

In the event of an internal or external audit you should be prepared to provide supporting documentation upon request. Auditors for government and commercial health plans will require documentation to support their payment for the drugs.

*If you cannot provide documentation supporting the off-label use, it is unlikely such use of the drugs will meet the health plan coverage requirements. You may need to find another payment source for these drugs. If you expect the patient to pay, this must be disclosed in the informed consent. Sponsor payments should be part of the sponsor agreement. Department funding is another alternative but will need to be secured through your department processes.