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NOTES FROM THE FIELD

Expressway to Cancer Clinical Trials: Reducing Administrative Barriers to Enrollment

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For nearly 20 years, the Michigan Cancer Consortium (MCC) has been involved in efforts with a variety of stakeholders to increase cancer patient participation in clinical trials. In 2001, the MCC partnered with the Michigan Working Group to Improve Cancer Outcomes on the development of the *Consensus Guidelines for Healthcare Coverage of Routine Patient Care Cost Associated with Oncology Clinical Trials*. The goal of this Consensus Agreement's creation was to increase participation in specific cancer-related clinical trials by supporting the predictability of payment for clinical trial services. The voluntary Consensus Agreement includes a framework detailing third party payer coverage of patient costs in relation to their benefit plan for clinical trial enrollment. Members of the Michigan Association of Health Plans supported the Consensus Agreement and agreed to increase participation in cancer-related clinical trials through coverage of routine costs associated with participation. A 2015 assessment supported by the MCC found clinical trial coverage through larger Michigan health plans (including Medicaid and Medicare) generally aligns with the Consensus Agreement.

With changes related to health care coverage through the Affordable Care Act and advancements in treatment, the MCC Board of Directors selected increasing cancer clinical trial enrollment as the 2016-2017 priority under the *Cancer Plan for Michigan's* Diagnosis and Treatment Goal in 2016. The MCC Clinical Trials Priority Workgroup was tasked with developing a project to support this effort. The workgroup convened with the goal to ensure Michigan residents with cancer who want to join a clinical trial can do so with fewer barriers. In 2016, 7 percent of Michigan adults who reported a cancer diagnosis also reported participating in cancer treatment clinical trials (Michigan Department of Health and Human Services, 2016).

The workgroup began by surveying stakeholders with the MCC and Michigan Society of Hematology and Oncology (MSHO) to assess barriers to clinical trial enrollment. Survey results indicated that providers had concerns with the sometimes-lengthy clinical trial enrollment process. As a result, the workgroup decided their project would address prior authorization concerns. Insurers often require prior authorization for cancer clinical trial enrollment, and ask for different pieces of information. This can lead to communication barriers between providers and insurers. In some instances, patient enrollment can be delayed by weeks while prior authorization is approved. The workgroup project focused on facilitating more rapid response to prior authorization requests by creating a fax cover sheet that could be shared with practitioners and used as a "heads up" when enrolling patients in cancer clinical trials.

The fax cover sheet was created for use when a health insurance carrier requires prior authorization for participation in a cancer clinical trial. It asks for such information as why the patient is eligible to participate, the therapeutic purpose for conducting the trial, and whether the trial is federally funded (see Appendix A for the fax cover sheet). Use of the fax cover sheet intends to simplify the prior authorization process and reduce the time needed to prepare and receive approval for authorization, thus decreasing the administrative burden for providers and insurers. The MCC Board of Directors approved the fax cover sheet in August 2016 and made it available as a fillable form on the [MCC Website](#).

After development of the fax cover sheet, the workgroup established a promotion plan for sharing it with various stakeholders and partners. Steps were taken to promote the fax cover sheet at the MCC Annual Meeting, on the MCC Website, at hospital cancer committee meetings, and with partner newsletters. Following promotion, an evaluation plan for determining the cover sheet's reach was also established. In 2017, it was downloaded from the MCC website 261 times. Questions about knowledge and use of the fax cover sheet were included in the 2017 MCC Annual Survey. MSHO members were also surveyed on similar questions in the fall of 2017. The results from both surveys (Figure 1) indicated there is still work to be done with promoting the fax cover sheet.

	Michigan Cancer Consortium Member Survey	Michigan Society of Hematology and Oncology Member Survey
Number of respondents (N=)	86	111
Aware of the cover sheet	23 (26.7%)	21 (18.9%)
Used the cover sheet in their office	3 (3.5%)	12 (10.9%)

Figure 1. Partner Knowledge and Use of the Clinical Trials Fax Cover Sheet Form

Over the next two years, the workgroup will continue to promote cancer clinical trial enrollment. A new project will be undertaken by the workgroup to develop infographics for patients and primary care providers, detailing the benefits of clinical trial enrollment. To support health equity, the infographics will meet accessibility guidelines. The MCC and Clinical Trials Priority Workgroup will remain dedicated to providing support and resources to increase the number of Michigan adults with cancer who participate in cancer clinical trials.

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References

1. Michigan Department of Health and Human Services. (2016) *Michigan Behavioral Risk Factor Surveillance System*.

Appendix A: MCC Clinical Trials Cover Sheet



The Michigan Cancer Consortium strongly supports facilitation of patient participation in cancer clinical trials.

This cover sheet was created for use when prior authorization for participation in a cancer clinical trial is required by a health insurance carrier

Cancer Clinical Trials Cover Sheet

Member

Date: _____

Last name: _____ First name: _____

ID #: _____ DOB: _____

Provider: _____ Facility: _____

Provider tax ID: _____ Facility tax ID: _____

Address: _____ Address: _____

Provider phone: _____ Fax: _____ Facility phone: _____ Fax: _____

Contact name: _____ Contact name: _____

Diagnosis: _____ Diagnosis code(s): _____

Brief description of trial (may attach copy of trial protocol): _____

Please provide the following information regarding the requested trial:

1. Member is eligible to participate in an approved clinical trial for treatment of one of the following:

- Cancer
- Other life-threatening disease/condition defined as: terminal illness, or a chronic, life-threatening, severely disabling disease that is causing serious clinical deterioration.

2. Therapeutic purpose for conducting the trial: disease prevention disease detection or diagnosis disease treatment

3. Clinical trial is a Phase I, Phase II, Phase III, or Phase IV clinical trial

4. Trial meets at least one of the following requirements (A, B, C, or D):

A. Federally funded trials approved or funded by one or more of the following (check all that apply):

- The National Institutes of Health
- The Centers for Disease Control and Prevention
- The Agency for Healthcare Research and Quality
- The Center for Medicare and Medicaid Services
- Cooperative group or center of any of the four entities listed above or the Department of Defense or the Department of Veterans Affairs
- Qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center-support grants
- The Department of Veterans Affairs; The Department of Defense; The Department of Energy when conditions described in the medical policy are met.

B. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration. Include IND number here: _____

C. The study or investigation is a drug trial that is exempt from having such an investigational new drug application. Name of trial sponsor here: _____

D. The study is a clinical evaluation of a legally marketed device with an Investigational Device Exemption (IDE) from the Food and Drug Administration. IDE number: _____

5. ClinicalTrials.gov Identifier: _____

Approved by the MCC Board of Directors: August 19, 2016