Information Sheet: Temporary Supplemental Funding for Shipment of CTEP IND Oral Agents to Patients

Beginning March 13, 2020, the NCI Pharmaceutical Management Branch provided interim guidance to allow site Dispensing Pharmacies to ship oral investigational agents directly to patients for trials under CTEP IND, including trials in the NCTN, due to the COVID-19 public health emergency. For current information about the status of this guidance and shipping and tracking requirements, please refer to the memo at: https://ctep.cancer.gov/content/docs/CTEP_Oral_IND_Agent_Shipments.pdf

While this interim guidance is in effect, NCI is providing temporary supplemental funding for NCTN trials to offset increased costs associated with shipping CTEP IND oral investigational agents to patients. This funding is intended to support the costs incurred by the site’s Dispensing Pharmacy in shipping the CTEP IND oral agents directly to patients during the period of the COVID-19 public health emergency.

What does my site need to do to receive this funding?

To receive payment for shipments of CTEP IND oral agents made on or after March 13, 2020, enter the shipment date in the OPEN funding screen just as you would a biospecimen collection date. If the Dispensing Pharmacy has made multiple shipments to a single patient, enter the date for each shipment.

How much funding will be provided?

For trials with CTEP IND oral agents that do not need to be refrigerated during shipping, $100 will be provided per shipment. For trials with oral agents that require a refrigerated shipping container, $140 will be provided per shipment.

For a small number of trials, the oral agents might either be refrigerated or non-refrigerated. In these cases, funding entries have been added to the trial for both the $100 (non-refrigerated) and $140 (refrigerated) funding levels. Sites should confirm with the site’s dispensing pharmacy how the oral agent was actually shipped and enter the shipment date in the appropriate level. Please note that as of July 2020, funding entries have been added for payments of up to 4 shipments to a single patient. More funding entries will be added as necessary.

How will this funding be distributed?

This funding will be distributed in the same way that federal funding for biospecimen collections is distributed.

- Rostered (Non-LAPS/Non-NCORP) Sites: For sites that receive their NCTN capitation funding directly from the credited NCTN Group, this temporary supplemental funding will be distributed through the usual funding mechanisms from the NCTN Group credited with the enrollment of the patient.

- LAPS and NCORP Sites: For sites that receive their NCTN funding from a LAPS or NCORP grant, the funding should be allocated from the current grant funding.
**Why is this funding not available for all trials with oral investigational agents?**

CTEP is able to provide this funding for trials under CTEP IND with oral investigational agents only.

Supplemental funding has not been added to CTEP IND trials if the oral investigational agent is expected to be dispensed in conjunction with other protocol therapy that requires a clinic visit. Oral investigational agents should only be shipped directly to patients when patients will not be seen in-person or the patients' representative cannot pick-up the drug at the local site.

**How can I tell if this funding is available for a specific trial?**

This new funding will show up as available in your site funding report in OPEN. Additionally, for trials with this funding available, a new funding entry has been added to the funding sheet with the funding amounts available for refrigerated or non-refrigerated agents, as appropriate for the trial:

<table>
<thead>
<tr>
<th>Funding Source and Study Component</th>
<th>Collect Type</th>
<th>Study Specific Notes</th>
<th>Enter Date in Open?</th>
<th>NCTN Funding per Patient Std &amp; HP LAPS</th>
<th>NCORP Funding per Patient Std &amp; HP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipments of CTEP IND Oral Agent to Patient – Non-refrigerated agent</td>
<td>Conditional</td>
<td>n/a</td>
<td>Yes</td>
<td>$100 per shipment</td>
<td>$100 per shipment</td>
</tr>
<tr>
<td>Shipments of CTEP IND Oral Agent to Patient – Refrigerated agent</td>
<td>Conditional</td>
<td>n/a</td>
<td>Yes</td>
<td>$140 per shipment</td>
<td>$140 per shipment</td>
</tr>
</tbody>
</table>

**Why is the funding type listed as “biospecimen” in the CTSU and OPEN systems?**

In order to distribute the funds as quickly as possible, we are using the existing “biospecimen” funding type for these payments with a specify designation that refers to this as shipping for CTEP IND oral agent(s). As a result, this funding will be listed as a “biospecimen” in the CTSU and OPEN systems and reports.