

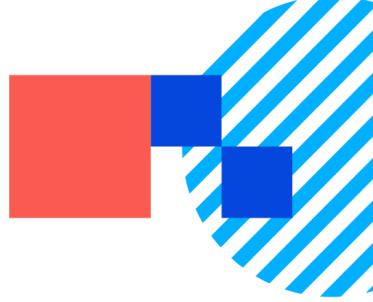
## Self-Administered Oncology Agents Prior Authorization

<b>Drug(s) Applied:</b>	<b>Alecensa</b> (alectinib)* <b>Avmapki-Fakzynja</b> Co-Pack (avutometinib and defactinib) <b>Ayvakit</b> (avapritinib) <b>Balversa</b> (erdafitinib) <b>BESREMI</b> peginterferon bexarotene <b>Bosulif</b> (bosutinib)* <b>Brukinsa</b> (zanubrutinib) <b>Calquence</b> (calabrutinib) <b>Caprelsa</b> (vandetanib) <b>Cometriq</b> (cabozantinib) <b>Copiktra</b> (duvelisib) <b>Cotellic</b> (cobimetinib) <b>Danziten</b> (nilotinib)* <b>dasatinib</b> * <b>Daurismo</b> (glasdegib) <b>Erivedge</b> (vismodegib) <b>erlotinib</b> <b>everolimus</b> <b>Fruzaqla</b> (fruquintinib)* <b>Gavreto</b> (pralsetinib) <b>gefitinib</b>	<b>Gilotrif</b> (afatinib) <b>Hernxeos</b> (zongertinib)* <b>Ibtrozi</b> (taletrectinib)* <b>Iclusig</b> (ponatinib)* <b>Idhifa</b> (enasidenib) <b>Inluriyo</b> (imlunestrant) <b>Inlyta</b> (axitinib) <b>Inqovi</b> (decitabine/cedazuridine) <b>Itovebi</b> (inavolisib) <b>Jakafi</b> (ruxolitinib) <b>Jaypirca</b> (pirtobrutinib)* <b>Kisqali</b> (ribociclib) <b>Kisqali Femara Pack</b> (ribociclib and letrozole) <b>Koselugo</b> (selumetinib) <b>Krazati</b> (adagrasib) <b>Ipatinib ditosylate</b> <b>Lazcluze</b> (lazertinib) <b>Lenalidomide</b> <b>Lenvima</b> (lenvatinib) <b>Lonsurf</b> (trifluridine/tipiracil) <b>Lorbrena</b> (lorlatinib)* <b>Lumakras</b> (sotorasib) <b>Lynparza</b> (olaparib)*	<b>Lysodren</b> (mitotane)* <b>Matulane</b> (procabazine) <b>Mekinist</b> (trametinib) <b>Modeyo</b> (dordaviprone) <b>Ninlaro</b> (ixazomib) <b>Nubeqa</b> (darolutamide) <b>Odomzo</b> (sonidegib) <b>Ojemda</b> (tovorafenib) <b>Ojaara</b> (momelotinib) <b>Onureg</b> (azacitidine) <b>pazopanib</b> * <b>Pemazyre</b> (pemigatinib) <b>Pomalyst</b> (pomalidomide) <b>Qinlock</b> (ripretinib) <b>Revuforj</b> (revumenib) <b>Rozlytrek</b> (entrectinib) <b>Rydapt</b> (midostaurin) <b>Scemblix</b> (asciminib)* <b>Stivarga</b> (regorafenib) <b>sunitinib</b> <b>Tabrecta</b> (capmatinib) <b>Tafinlar</b> (dabrafenib) <b>Tagrisso</b> (osimertinib)	<b>Talzenna</b> (talazoparib)* <b>Tazverik</b> (tazemetostat) <b>temozolomide</b> <b>Thalomid</b> (thalidomide) <b>Tibsovo</b> (ivosidenib) <b>Tretinoiin caps</b> (all-trans retinoic acid) <b>Truqap</b> (capivasertib) <b>Tukysa</b> (tucatinib) <b>Venclexta</b> (venetoclax) <b>Verzenio</b> (abemaciclib) <b>Vitrakvi</b> (larotrectinib) <b>Welireg</b> (belzutifan) <b>Xospata</b> (gilteritinib) <b>Xtandi</b> (enzalutamide) <b>Zelboraf</b> (vemurafenib) <b>Zolinza</b> (vorinostat) <b>Zydelig</b> (idelalisib)
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Requests for multi-drug therapies should be reviewed together as a regimen.

\*drug specific criteria applies





## Universal Criteria:

Drug(s) applied will be approved when all of the following criteria are met:

### I. Initial Therapy Criteria

- A. **All oncology indications** as indicated by chart notes within past 180 days
  - 1. ONE of the following:
    - a) Patient has an FDA approved indication for the patient's age and requested agent/regimen **or**
    - b) Patient has an indication that is supported by NCCN category 1 or 2A recommended use, [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous therapies, monotherapy vs combination therapy, patient age, etc.)] for the requested agent/regimen **and**
  - 2. Requested agent/regimen is not being used after disease progression on the same drug or a drug with the same mechanism of action, which is considered experimental/investigational unless otherwise explicitly stated within the NCCN Compendium **and**
  - 3. Dose, frequency, and total duration of authorization does not exceed that listed within the FDA-approved prescribing information or NCCN Compendium for the complete regimen **and**
  - 4. Requested agent is not being used for an FDA indication withdrawn from the market, irrespective of NCCN Compendium or additional compendia position **and**
  - 5. Meets the drug specific criteria below if requested agent is listed

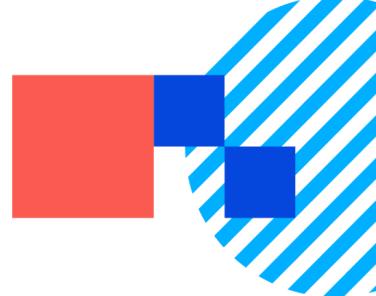
**Approval Duration:** 12 months for all agents, EXCEPT:

Approval Duration: 6 months for new starts and continuation			
<b>Balversa</b> (erdafitinib) <b>Fruzaqla</b> (fruquintinib) <b>Inluriyo</b> (imlunestrant) <b>Krazati</b> (adagrasib)	<b>Lonsurf</b> (trifluridine/ tipiracil) <b>Lumakras</b> (sotorasib) <b>Pemazyre</b> (pemigatinib)	<b>Qinlock</b> (ripretinib) <b>Revuforj</b> (revumenib) <b>Stivarga</b> (regorafenib) <b>Tabrecta</b> (capmatinib) <b>Talzenna</b> (talazoparib)	<b>Tibsovo</b> (ivosidenib) <b>Truqap</b> (capivasertib) <b>Zolinza</b> (vorinostat)

### II. Continued Therapy Criteria

- A. **All oncology indications** as indicated by chart notes within past 180 days
  - 1. Chart notes indicate patient has been treated with the requested agent/regimen and is a continuation of therapy (starting on samples is not approvable) **and**
  - 2. For metastatic solid tumors, must receive imaging within the past 3 months **and**





3. ONE of the following:
  - a) Patient has an FDA approved indication for the patient's age and requested agent/regimen **or**
  - b) Patient has an indication that is supported by NCCN category 1 or 2A recommended use, [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous therapies, monotherapy vs combination therapy, patient age, etc.)] for the requested agent/regimen **and**
4. Requested agent/regimen is not being used beyond disease progression on the same drug or a drug with the same mechanism of action, which is considered experimental/investigational unless otherwise explicitly stated within the NCCN Compendium **and**
5. Dose, frequency, and total duration of authorization does not exceed that listed within the FDA-approved prescribing information, the NCCN Compendium for the complete regimen **and**
6. If the requested agent is being used for an FDA-approved indication recently withdrawn from the market, imaging performed within the past 3 months demonstrates the patient is still benefiting from therapy without evidence of disease progression

**Approval Duration:** Up to 12 months for all agents, EXCEPT:

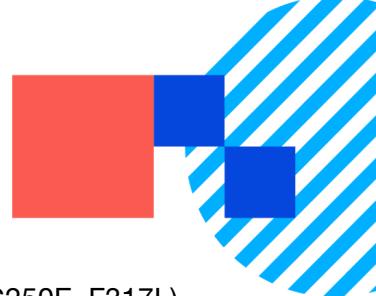
Approval Duration: 6 months for new starts and continuation			
<b>Balversa</b> (erdafitinib) <b>Fruzaqla</b> (fruquintinib) <b>Inluriyo</b> (imlunestrant) <b>Krazati</b> (adagrasib)	<b>Lonsurf</b> (trifluridine/ tipiracil) <b>Lumakras</b> (sotorasib) <b>Pemazyre</b> (pemigatinib)	<b>Qinlock</b> (ripretinib) <b>Revuforj</b> (revumenib) <b>Stivarga</b> (regorafenib) <b>Tabrecta</b> (capmatinib) <b>Talzenna</b> (talazoparib)	<b>Tibsovo</b> (ivosidenib) <b>Truqap</b> (capiwasertib) <b>Zolinza</b> (vorinostat)

#### Drug Specific Criteria:

Drug(s) applied will be approved when all of the following criteria are met:

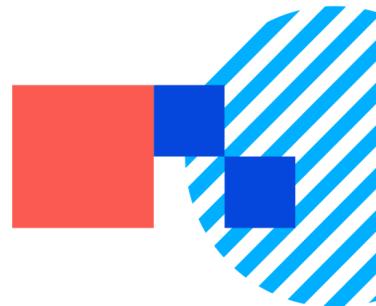
- I. Initial Therapy Criteria, in addition to the Universal Criteria above
  - A. **Alecensa**- may still be used if disease progression on Xalkori (NF)
  - B. **Bosulif**- ALL of the following:
    - Patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and
    - Must be a documented contraindication, intolerance, or resistance to imatinib and





- Must not have a contraindicated mutation (e.g. T315I, V299L, G250E, F317L)
- C. **Danzitentnilotinib**- patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and must be a documented contraindication, intolerance, or resistance to imatinib
- D. **Dasatinib**- patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and must be a documented contraindication, intolerance, or resistance to imatinib and must not have a contraindicated mutation (e.g. T315I, T315A, V299L, F317L, F317V, F317I, F317C)
- E. **Fruzaqla**- ALL of the following:
  - Must be used as fourth (4th) line of therapy after prior fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin, irinotecan, anti-VEGF therapy (ex: bevacizumab) **and**
  - If RAS wild-type, must have tried/failed an anti-EGFR therapy (ex: cetuximab or panitumumab) **and**
  - If dMMR/MSI-H or POLE/POLD1 mutation with ultra-hypermutated phenotype [eg, TMB>50 mut/Mb], must have tried/failed an immune checkpoint inhibitor
- F. **Hernexeos**- must have documented disease progression on Enhertu IV (medical benefit)
- G. **Ibtrozi**- must have documented the G2032R ROS1 resistance mutation
- H. **Iclusig**- ONE of the following:
  - Patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and must be a documented contraindication, intolerance, or resistance to imatinib and one (1) other therapy or
  - Patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and have a T315I resistance mutation
- I. **Jaypirca**- ONE of the following:
  - Patient must be an adult with relapsed or refractory mantle cell lymphoma (MCL) and has experienced disease progression on or following at least two (2) lines of systemic therapy, including a BTK inhibitor or
  - Patient must be an adult with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) and has experienced disease progression on or following at least two (2) prior lines of therapy, including a BTK inhibitor and Venclexta
- J. **Lorbrena**- may still be used if disease progression on Xalkori (NF) and/or one (1) other ALK inhibitor (e.g. Alecensa)
- K. **Lynparza**- must not have experienced disease progression on another PARP inhibitor





- L. **Lysodren**- patient has an oncology-related indication
- M. **Pazopanib 200mg tabs**- must have a documented intolerance to pazopanib 400mg tabs that is not expected to occur with the 200mg tabs
- N. **Scemblix**- ALL of the following:
  - Must not be used in combination with dasatinib for relapsed/refractory Ph+ B-ALL and
  - ONE of the following:
    - a) Patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and must be a documented contraindication, intolerance, or resistance to imatinib and one (1) other therapy or
    - b) Patient must have chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (Ph+ ALL) and have a T315I resistance mutation
- O. **Talzenna**- ALL of the following:
  - Must not have experienced disease progression on another PARP inhibitor and
  - If for germline BRCA-mutated, HER2- locally advanced or metastatic breast cancer, there must be a documented contraindication or intolerance to Lynparza

**Policy Owned by:** Curative PBM team

