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Self-Administered Oncology Agents Prior Authorization

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

Requests for multi-drug therapies should be reviewed together as a regimen.
*drug specific criteria applies

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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 <u>not</u> 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			
Balversa (erdafitinib) **Fruzaqla** (fruquintinib) **Inluriyo** (imlunestrant) **Krazati** (adagrasib)	**Lonsurf** (trifluridine/ tipiracil) **Lumakras** (sotorasib) **Pemazyre** (pemigatinib)	**Qinlock** (ripretinib) **Revuforj** (revumenib) **Stivarga** (regorafenib) **Tabrecta** (capmatinib) **Talzenna** (talazoparib)	**Tibsovo** (ivosidenib) **Truqap** (capivasertib) **Zolinza** (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			
Balversa (erdafitinib) **Fruzaqla** (fruquintinib) **Inluriyo** (imlunestrant) **Krazati** (adagrasib)	**Lonsurf** (trifluridine/ tipiracil) **Lumakras** (sotorasib) **Pemazyre** (pemigatinib)	**Qinlock** (ripretinib) **Revuforj** (revumenib) **Stivarga** (regorafenib) **Tabrecta** (capmatinib) **Talzenna** (talazoparib)	**Tibsovo** (ivosidenib) **Truqap** (capivasertib) **Zolinza** (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. **Danziten/nilotinib-** 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 hot 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