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Self-Administered Oncology Agents
Prior Authorization Drug List A

Drug(s) Applied:				
	Alecensa (alectinib)* **Alunbrig** (brigatinib)* **Avmapki-Fakzynja** Co-Pack (avutometinib and defactinib) **Ayvakit** (avapritinib) **Balversa** (erdafitinib) **BESREMi** peginterferon **bexarotene** **Bosulif** (bosutinib)* **Braftovi** (encorafenib)* **Brukinsa** (zanubrutinib) **Calquence** (calabrutinib) **Caprelsa** (vandetanib) **Cometriq** (cabozantinib) **Copiktra** (duvelisib) **Cotellic** (cobimetinib) **Danziten** (nilotinib)* **dasatinib*** **Daurismo** (glasdegib) **Erivedge** (vismodegib) **Erleada** (apalutamide)* **erlotinib** **everolimus** **Fotivda** (tivozanib) **Fruzaqla** (fruquintinib)* **Gavreto** (pralsetinib) **gefitinib**	**Gilotrif** (afatinib) **Hernexeos** (zongertinib)* **Hycamtin** (topotecan) **Ibrance** (palbociclib)* **Ibtrozi** (taletrectinib)* **Iclusig** (ponatinib)* **Idhifa** (enasidenib) **Imbruvica** (ibrutinib)* **Inluriyo** (imlunestrant)* **Inlyta** (axitinib) **Inqovi** (decitabine/cedazuridine) **Inrebic** (fedratinib)* **Itovebi** (inavolisib) **Jakafi** (ruxolitinib) **Jaypirca** (pirtobrutinib)* **Kisqali** (ribociclib) **Kisqali Femara Pack** (ribociclib and letrozole) **Koselugo** (selumetinib) **Krazati** (adagrasib) **lapatinib ditosylate** **Lazcluze** (lazertinib) **lenalidomide** **Lenvima** (lenvatinib) **Lonsurf** (trifluridine/ tipiracil) **Lorbrena** (lorlatinib)* **Lumakras** (sotorasib) **Lynparza** (olaparib)*	**Lysodren** (mitotane)* **Matulane** (procarbazine) **Mekinist** (trametinib) **Mektovi** (binimetinib)* **Modeyso** (dordaviprone) **Nerlynx** (neratinib) **Nilotinib D-tartrate*** **Nilutamide*** **Ninlaro** (ixazomib) **Nubeqa** (darolutamide) **Odomzo** (sonidegib) **Ojemda** (tovorafenib) **Ojjaara** (momelotinib) **Onureg** (azacitidine) **pazopanib*** **Pemazyre** (pemigatinib) **Piqray** (alpelisib) **Pomalyst** (pomalidomide) **Qinlock** (ripretinib) **Retevmo** (selpercatinib) **Revuforj** (revumenib) **Rozlytrek** (entrectinib) **Rubraca** (rucaparib)* **Rydapt** (midostaurin) **Scemblix** (asciminib)* **Soltamox** (tamoxifen)* **Stivarga** (regorafenib) **sunitinib** **Tabrecta** (capmatinib) **Tafinlar** (dabrafenib) **Tagrisso** (osimertinib)	**Talzenna** (talazoparib)* **Tasigna** (nilotinib)* **Tazverik** (tazemetostat) **Temozolomide** **Tepmetko** (tepotanib)* **Thalomid** (thalidomide) **Tibsovo** (ivosidenib) **Tretinoin caps** (all-trans retinoic acid) **Truqap** (capivasertib) **Tukysa** (tucatinib) **Turalio** (pexidartinib)* **Venclexta** (venetoclax) **Verzenio** (abemaciclib) **Vitrakvi** (larotrectinib) **Vizimpro** (dacomitinib)* **Welireg** (belzutifan) **Xalkori** (crizotinib) **Xospata** (gilteritinib) **Xpovio** (selinexor) **Xtandi** (enzalutamide) **Yonsa** (abiraterone acetate micronized)* **Zejula** (niraparib)* **Zelboraf** (vemurafenib) **Zolinza** (vorinostat) **Zydelig** (idelalisib) **Zykadia** (ceritinib)*

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) **Fotivda** (tivozanib) **Fruzaqla** (fruquintinib) **Hycamtin,** topotecan **Inluriyo** (imlunestrant) **Krazati** (adagrasib)	**Lonsurf** (trifluridine/ tipiracil) **Lumakras** (sotorasib) **Nerlynx** (neratinib) **Pemazyre** (pemigatinib) **Piqray** (alpelisib)	**Qinlock** (ripretinib) **Revuforj** (revumenib) **Stivarga** (regorafenib) **Tabrecta** (capmatinib) **Talzenna** (talazoparib) **Tepmetko** (tepotinib)	**Tibsovo** (ivosidenib) **Truqap** (capivasertib) **Xpovio** (selinexor) **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:

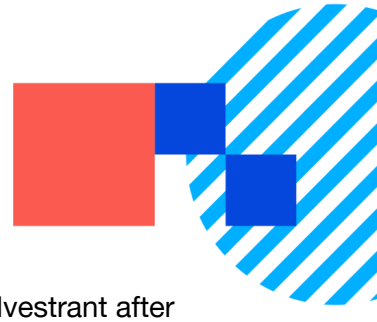
Approval Duration: 6 months for new starts and continuation			
Balversa (erdafitinib) **Fotivda** (tivozanib) **Fruzaqla** (fruquintinib) **Hycamtin,** topotecan **Inluriyo** (imlunestrant) **Krazati** (adagrasib)	**Lonsurf** (trifluridine/ tipiracil) **Lumakras** (sotorasib) **Nerlynx** (neratinib) **Pemazyre** (pemigatinib) **Piqray** (alpelisib)	**Qinlock** (ripretinib) **Revuforj** (revumenib) **Stivarga** (regorafenib) **Tabrecta** (capmatinib) **Talzenna** (talazoparib) **Tepmetko** (tepotinib)	**Tibsovo** (ivosidenib) **Truqap** (capivasertib) **Xpovio** (selinexor) **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
- **Alecensa-** may still be used if disease progression on Xalkori
- **Alunbrig-** must have documented contraindication or intolerance without disease progression to Alecensa
- **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)

- **Braftovi with Mektovi-** must have documented intolerance to prior Tafinlar plus Mekinist therapy without evidence of disease progression for all shared indications (ex: melanoma, non-small cell lung cancer)
- **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
- **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)
- **Erleada-** ONE of the following:
  - For **non-**metastatic castration **sensitive** prostate cancer, must be a documented contraindication or intolerance to abiraterone acetate and Xtandi **or**
  - For metastatic castration **sensitive** prostate cancer, must be a documented contraindication or intolerance to abiraterone acetate, Xtandi, and Nubeqa **or**
  - For **non-**metastatic castration **resistant** prostate cancer, must be a documented contraindication or intolerance to Xtandi and Nubeqa
- **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
- **Hernexeos-** must have documented disease progression on Enhertu IV (medical benefit)
- **Ibrance**-
  - Patient must be an adult with HR+/HER2- recurrent unresectable, advanced, or metastatic breast cancer and
    - One of the following:
      - Patient will be taking Ibrance in combination with an aromatase inhibitor (e.g., letrozole) as initial endocrine based therapy or



        - Patient will be using Ibrance in combination with fulvestrant after disease progression on or following endocrine-based therapy (e.g., anastrozole) and
    - If initial therapy, there must be a documented contraindication or intolerance to Kisqali AND Verzenio **or**
  - Patient must be an adult with PIK3CA-mutated, HR+/HER2- recurrent unresectable, advanced, or metastatic breast cancer and
    - Patient has experienced recurrence on or after adjuvant (post-operative) endocrine therapy (e.g., anastrozole, letrozole, exemestane, tamoxifen) for non-metastatic disease, and patient will be using Ibrance in combination with Itovebi and fulvestrant
- **Ibtrozi**- must have documented the G2032R ROS1 resistance mutation
- **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
- **Imbruvica caps**- must have tried and had documented adverse reactions to Brukinsa and Calquence in indications where they are preferred or have the same level of NCCN recommendation as Imbruvica for the indication
- **Inluriyo-** ALL of the following:
  - must have tried and had documented disease progression on palbociclib, ribociclib, or abemaciclib; **and**
  - must not have experienced disease progression while receiving an oral SERD (e.g., Orserdu, camizestrant) or PROTAC estrogen receptor degrader (e.g., vepdegestrant)
- **Inrebic**- must have tried and had documented disease progression on Jakafi
- **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
- **Lorbrena**- may still be used if disease progression on Xalkori and/or one (1) other ALK inhibitor (e.g. Alecensa)

- **Lynparza**- must not have experienced disease progression on another PARP inhibitor
- **Lysodren**- patient has an oncology-related indication
- **Nilotinib D-tartrate-** for chronic myeloid leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), there must be a documented contraindication, intolerance, or resistance to imatinib and Curative's covered nilotinib-based product
- **Nilutamide-** must be a documented contraindication or intolerance to bicalutamide
- **Pazopanib 200mg tabs-** must have a documented intolerance to pazopanib 400mg tabs that is not expected to occur with the 200mg tabs
- **Rubraca**- ALL of the following:
  - Must not have experienced disease progression on another PARP inhibitor and
  - Must be a documented contraindication or intolerance to Lynparza, unless treating PALB2+ pancreatic cancer
- **Scemblix**- ALL of the following:
  - Must not be used in combination with dasatinib for relapsed/refractory Ph+ B-ALL and
  - 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
- **Soltamox**- must have documented inability to swallow tablets or require administration via feeding tube
- **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
- **Tasigna-** for chronic myeloid leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), there must be a documented contraindication, intolerance, or resistance to imatinib and nilotinib
- **Tepmetko-** must have documented intolerance to prior Tabrecta (capmatinib) therapy without evidence of disease progression

- **Turalio-** Patient has symptomatic tenosynovial giant cell tumor (TGCT) with severe morbidity or functional limitations and patient is not a surgical candidate
- **Vizimpro**- must have tried and had documented adverse reactions to Tagrisso or Lazcluse with Rybrevant
- **Yonsa**- must have documented contraindication or intolerance without disease progression to abiraterone acetate 250mg tablets
- **Zejula**- ALL of the following:
  - Must not have experienced disease progression on another PARP inhibitor and
  - If for metastatic castration-resistant prostate cancer (mCRPC), must be a documented intolerance without disease progression to Akeega (NF)
- **Zykadia**- may still be used if progression on Xalkori

Policy Owned by: Curative PBM team