|  |  |  |
| --- | --- | --- |
| 9.2024 תיעדוף תרופות אונקולוגיות ע"י האיגוד האונקולוגי | | |
| **דירוג תרופות** | | |
| 1 | Durvalumab | Imfinzi is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT). |
| 2 | Alectinib | Alecensa is indicated as adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by a validated test. |
| 3 | Osimertinib | Tagrisso is indicated for the treatment of adult patients with locally advanced, unresectable (Stage III) NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, and whose disease has not progressed following platinum-based chemoradiation therapy. (LAURA) |
| 4 | Pembrolizumab | Pembrolizumab (Keytruda), as a single agent, is indicated for the adjuvant treatment following resection and platinum-based chemotherapy, of patients with Stage IB (T2a ≥4 cm), II, or IIIA NSCLC (KN091). |
| 5 | Pembrolizumab | Pembrolizumab (KEYTRUDA), in combination with chemoradiotherapy (CRT), is indicated for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer. |
| 6 | Ribociclib | Kisqali is indicated for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer, irrespective of nodal status, in combination with an aromatase inhibitor. a. more than 4 positive lymph nodes. b. 1-3 positive lymph nodes and tumor size above 5 cm or G3 or KI67>20" |
| 7 | Enfortumab Vedotin  +  Pembrolizumab | PADCEV, in combination with pembrolizumab, is indicated for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC).  Pembrolizumab, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer. |
| 8 | Dostarlimab | Jemperli is indicated in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy. |
| 8 | Pembrolizumab | Pembrolizumab (KEYTRUDA), in combination with chemotherapy, followed by KEYTRUDA as a single agent is indicated for the treatment of patients with primary advanced or recurrent endometrial carcinoma. (dMMR) |
| 8 | Durvalumab | IMFINZI in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with: IMFINZI as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR). |
| 9 | Ripretinib | Treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. |
| 10 | Trastuzumab deruxtecan | ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. |
| 11 | Nivolumab | In combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with unresectable advanced or metastatic gastric cancer or gastroesophageal junction cancer. Stomach\GEJ adenocarcinoma only .CPS≥5% |
| 11 | Pembrolizumab | Pembrolizumab (KEYTRUDA) in combination with fluoropyrimidine- and platinum-containing chemotherapy is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma. (KN859) – Stomach\GEJ CPS≥5% |
| 11 | Nivolumab | In combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of patients with unresectable advanced or metastatic esophageal adenocarcinoma. CPS≥5% |
| 11 | Pembrolizumab | Treatment of patients with locally advanced or metastatic esophageal or ~~gastroesophageal junction~~ (GEJ) (Siewert type 1) carcinoma that is not amenable to surgical resection or definitive chemoradiation, in combination with platinum and fluoropyrimidine-based chemotherapy. (KN590) adenocarcinoma + squamous cell carcinoma CPS≥5% |
| 12 | Vorasidenib | Treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation in adult and pediatric patients 12 years and older following surgical intervention. Test for detection of IDH mutation . INDIGO Trial, phase III, placebo-controlled |
| 13 | Trastuzumab deruxtecan | ENHERTU is indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. HER2-Positive (IHC 3+). DESTINY-gastric-01 |
| 13 | Trastuzumab deruxtecan | ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. DESTINY pan tumor-02 |
| 14 | Amivantamab | RYBREVANT is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an approved test. |
| 15 | Encorafenib  + Cetuximab | Encorafenib is indicated in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an approved test after prior therapy. |
| 16 | Selpercatinib | Treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC). |
| 17 | Selpercatinib | RETEVMO is indicated for the treatment of adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. Select patients for treatment with RETEVMO based on the presence of a RET gene fusion (NSCLC or thyroid cancer, or other solid tumors) or specific RET gene mutation (MTC) in tumor specimens or plasma. |
| 18 | Belzutifan | Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for VHL associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable. |
| 19 | Amivantamab | RYBREVANT (amivantamab) in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including a third-generation EGFR tyrosine kinase inhibitor (TKI). |
| 20 | Trifluridine Tipiracil  +  Bevacizumab | Lonsurf is indicated in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents. |
| 20 | Fruquitinib | Treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine, oxaliplatin, and irinotecan‑based chemotherapy, an anti‑VEGF therapy, and, if RAS wild‑type, an anti-EGFR therapy. |
| 21 | Durvalumab | Imfinzi in combination with etoposide and either carboplatin or cisplatin is indicated for the first line treatment of patients with extensive-stage small cell lung cancer. |
| 21 |  | TECENTRIQ, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). |
| 22 | Trastuzumab Deruxtecan | ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an approved test, and who have received a prior systemic therapy. |
| 23 | Pembrolizumab | Pembrolizumab (KEYTRUDA), in combination with chemotherapy, followed by KEYTRUDA as a single agent is indicated for the treatment of patients with primary advanced or recurrent endometrial carcinoma. |
| 24 | Durvalumab | IMFINZI in combination with gemcitabine and cisplatin is indicated for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer (BTC). |
| 25 | Sacituzumab govitecan | Trodelvy is indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. |
| 26 | Mirvetuximab soravtansine (MIRV) | Mirvetuximab soravtansineis a FRα-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with FRα positive, platinum resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. |
| 27 | 177Lu-PSMA | Pluvicto is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy ~~or who are not medically suitable for taxanes.~~ |
| 28 | Enfortumab Vedotin | PADCEV, as a single agent, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who: have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy |
| 29 | Ivosidenib | TIBSOVO is indicated for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test\* |
| 30 | Pembrolizumab | Pembrolizumab (Keytruda), is indicated for the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. |
| 30 | Durvalumab | IMFINZI in combination with chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. |
| 30 | Nivolumab | OPDIVO, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors >4 cm or node positive) NSCLC, followed by OPDIVO as a single agent in the adjuvant setting after surgical resection. |
| 31 | Ribociclib | Kisqali is indicated for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer, irrespective of nodal status, in combination with an aromatase inhibitor  For a sub-group: **N1 (1-3 positive lymph nodes)** with high genomic risk (as defined for each genomic test) followed by Ribociclib combination with an aromatase inhibitor |
| 32-65 | of list | The rest |
|  | | |
| **טכנולוגיות** | | |
| 1 | NGS בדיקת פרופיל מולקולרי של גידולים סולידיים | להרחיב את אוכלוסיית חולי הסרטן הזכאים לאפיון גנומי מקיף של הגידול הסרטני ולהתאמת טיפול תרופתי על בסיסו - לכל חולי הסרטן המאובחנים בשלב המתקדם/גרורתי של מחלתם. |
| 2 | LITT (Laser Interstitial Thermal Therapy) | טיפול בגרורות מוחיות עמוקות, הגדלות לאחר טיפול קרינתי ממוקד (כישלון של טיפול רדיו-כירורגי) |
| 3 | טיפול בדיקור | חולים בסרטן המקבלים טיפול כימותרפי, ביולוגי/אימונולוגי, ניתוחי ו/או פליאטיבי הסובלים מכאב- ביטול המגבלה לשימוש במסגרת מרפאת כאב |
| 4 | PET FDG | מעקב אחר מטופלים שאובחנו עם קרצינומה של קורטקס אדרנל: לאחר טיפול ניתוחי- להערכה של הישנות הגידול במהלך טיפול כימותרפיה- להערכת תגובה |

בכבוד רב,

חברי ועדת האיגוד לתיעדוף התרופות –ד"ר יקטרינה שולמן (יו"ר), ד"ר עפר רותם, ד"ר שלומית סטרולוב-שחר, ד"' יגאל קושניר וד"ר מור מיודובניק

פרופ' גיל בר סלע, יו"ר האיגוד הישראלי לאונקולוגיה קלינית ורדיותרפיה  
פרופ' עידו וולף, יו"ר המועצה הלאומית למניעה, אבחון וטיפול במחלות ממאירות