Summary of Changes – 10/1/26

Keytruda Qlex SGM 7197-A 2026a – For Exclusions, added exception for use with trametinib/dabrafenib per NCCN. For cutaneous melanoma, removed requirement that disease must be progressive for subsequent treatment, per NCCN. For NSCLC, added RET and ROS1 as contraindicated biomarkers per NCCN. For PDL1 positive disease, added requirement as single agent per NCCN. Added coverage for adjuvant single agent use after adjuvant chemotherapy per NCCN. For urothelial cancer of the bladder, added coverage for recurrent disease per NCCN. For primary cancer of the urethra, removed coverage for locally advanced disease post-chemotherapy per NCCN. For small bowel adenocarcinoma, added coverage for neoadjuvant therapy, per NCCN. For Merkel cell carcinoma, added coverage for regional disease per NCCN. For gastric cancer, per NCCN: specified adenocarcinoma histology, added first-line/primary treatment requirement for PD-L1 positive disease. For esophageal cancer, added first-line requirement for PD-L1 positive disease per NCCN. For ovarian cancer, added coverage for subsequent treatment in combination with paclitaxel with/without bevacizumab for PD-L1 positive disease per FDA label update and NCCN. Added coverage for small cell carcinoma of the ovary (hypercalcemic type), per NCCN.

Removed coverage for testicular cancer per NCCN. For anal carcinoma, added coverage for use with paclitaxel and carboplatin, per NCCN.

For CNS brain metastases, specified melanoma is BRAF non-specific per NCCN.

For biliary tract cancer neoadjuvant treatment, added option in combination with carboplatin per NCCN.

For hepatocellular carcinoma, updated criteria for single agent subsequent therapy per NCCN.

For vulvar cancer, added requirement that single agent therapy is subsequent per NCCN.

For RCC first-line, added coverage as single agent per Lexi-Drugs. For subsequent therapy, removed requirement for clear cell histology per NCCN.

For cutaneous squamous cell carcinoma, added coverage for satellitosis/in-transit metastasis per NCCN. For soft tissue sarcoma, added coverage for neoadjuvant and

adjuvant therapy for UPS related sarcomas, per NCCN.

For soft tissue sarcoma, added clinical settings for subsequent treatment and 'pleomorphic' rhabdomyosarcoma per NCCN. For breast cancer, added coverage for use in combination with sacituzumab govitecan-hziy in members with no response to preoperative systemic therapy or for recurrent unresectable or metastatic TNBC, per NCCN.

For PD-L1 positive breast cancer, specified CPS 10 or greater and removed single agent use per NCCN.

For prostate cancer, removed requirement for subsequent treatment and removed coverage of MSI-H/dMMR disease.

For Kaposi sarcoma, added criteria for advanced disease per NCCN.

For vaginal cancer in combination with chemotherapy, added requirement for PD-L1 positive disease per NCCN. Removed criteria for TMB-H disease per NCCN.

For penial cancer, added requirement for first-line therapy when used with chemotherapy per NCCN.

Added coverage for chordoma per NCCN.

Keytruda SGM 1889-A 2026a – For Exclusions, added exception for use with trametinib/dabrafenib per NCCN. For cutaneous melanoma, removed requirement that disease must be progressive for subsequent treatment, per NCCN. For NSCLC, added RET and ROS1 as contraindicated biomarkers per NCCN. For PDL1 positive disease, added requirement as single agent per NCCN. Added coverage for adjuvant single agent use after adjuvant chemotherapy per NCCN. For urothelial cancer of the bladder, added coverage for recurrent disease per NCCN. For primary cancer of the urethra, removed coverage for locally advanced disease post-chemotherapy per NCCN. For small bowel adenocarcinoma, added coverage for neoadjuvant therapy, per NCCN. For Merkel cell carcinoma, added coverage for regional disease per NCCN. For gastric cancer, per NCCN: specified adenocarcinoma histology, added first-line/primary treatment requirement for PD-L1 positive disease. For esophageal cancer, added first-line requirement for PD-L1 positive disease per NCCN. For ovarian cancer, added coverage for subsequent

treatment in combination with paclitaxel with/without bevacizumab for PD-L1 positive disease per FDA label update and NCCN. Added coverage for small cell carcinoma of the ovary (hypercalcemic type), per NCCN.

bexarotene-Targretin SGM 1795-A 2026 – Removed coverage for Adult T-cell leukemia/lymphoma under the gel formulation per NCCN.

Valchlor SGM 1862-A 2026 – Removed coverage for Adult T-Cell Leukemia/Lymphoma, per NCCN.

Datroway SGM 6816-A 2026a – For the treatment of HR-positive breast cancer, specified use as a single agent and that the member is not an candidate for treatment with fam-trastuzumab deruxtecan-nxki (Enhertu), per NCCN.

Added coverage for triple negative breast cancer, per NCCN.

For the treatment of NSCLC, added coverage for recurrent disease and removed the requirement that the member must have received prior treatment with EGFR directed therapy and platinum based chemotherapy, per NCCN.

Talzenna SGM 2782-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer, per NCCN.

Removed requirement that prostate cancer has not be treated in metastatic setting, per NCCN.

Updated verbiage for prostate cancer from has not progressed on prior novel hormone therapy to member has not received androgen receptor pathway inhibitor (ARPI) therapy, per NCCN.

Lynparza SGM 1810-A 2026 – Removed use in combination with Yonsa (fine-particle abiraterone) for prostate cancer due to lack of compendial support.

Updated verbiage for prostate cancer from has not progressed on prior novel hormone therapy to member has not received androgen receptor pathway inhibitor (ARPI) therapy, per NCCN.

Trodelvy SGM 3818-A 2026a – For triple negative breast cancer, removed requirement that member has received at least one prior regimen when used as a single agent per NCCN, and added coverage for use as first-line therapy in combination with Keytruda for PD-L1 positive disease per NCCN. Added documentation requirement for PD-L1 status.

For urothelial carcinoma – bladder cancer, added coverage for Stage 3 disease per NCCN

Yervoy SGM 1796-A 2026 – Updated appendiceal adenocarcinoma to appendiceal neoplasms and appendiceal cancers to align with NCCN.

Added coverage for dedifferentiated liposarcoma and epithelioid hemangioendothelioma, per NCCN.

Added coverage for in-transit disease for Merkel cell carcinoma, per NCCN.

Added coverage for cervical cancer, adrenal gland tumors, uterine neoplasms, vaginal cancer and vulvar cancer, per NCCN.

Updated continuation of therapy for peritoneal mesothelioma to a maximum of 24 months of treatment, per NCCN.

Opdivo SGM 1894-A 2026 – Removed coverage for subsequent treatment of stage II, recurrent and persistent urothelial carcinoma bladder cancer due to lack of compendial support. For Merkel cell carcinoma added coverage for regional and in transit disease when used in combination with ipilimumab and regional disease when used as a single agent, per NCCN. Endometrial carcinoma updated from recurrent to recurrent unresectable and added coverage for metastatic disease, per NCCN. Added coverage for uterine sarcoma, per NCCN. Added requirement for PD-L1≥ 1 gastric cancer that disease is HER 2 negative, per NCCN. Added coverage for vulvar cancer, cervical cancer, vaginal cancer and adrenal gland tumors in combination with ipilimumab, per NCCN. Added requirement for Kaposi sarcoma that disease is advanced, per NCCN.

Opdivo Qvantig SGM 6795-A 2026 – Added coverage for appendiceal neoplasms and cancers, anal carcinoma, Merkel cell carcinoma, CNS brain metastases, gestational trophoblastic neoplasia, pleural or peritoneal mesothelioma, endometrial carcinoma, vulvar cancer, small cell lung cancer, cervical cancer, Kaposi sarcoma, bone cancer, soft tissue sarcoma, anaplastic thyroid carcinoma, histologic (Richter) transformation to diffuse large B-cell lymphoma, vaginal cancer, squamous cell skin carcinoma, ampullary adenocarcinoma, small bowel adenocarcinoma, per NCCN.

Updated continuation of therapy language for renal cell carcinoma to a maximum of 24 months of treatment when used in combination with cabozantinib, per NCCN.

Perjeta and Pertuzumab Biosimilars SGM 1899-A 2026a – Added FDA approved biosimilar, Poherdy.

For breast cancer, added requirement for clinical stage for adjuvant treatment per Label and NCCN. Updated verbiage from recurrent to recurrent unresectable disease to align with NCCN. Added coverage in combination with Enhertu or aromatase inhibitor, Ibrance and trastuzumab per NCCN. Added documentation requirement for HR status

For colorectal cancer, added coverage for initial treatment of unresectable metachronous metastases per NCCN.

For appendiceal neoplasms and cancers, added coverage for goblet cell adenocarcinoma and undifferentiated carcinoma not otherwise specified per NCCN. Added requirement that member has not received previous treatment with HER2 inhibitor per NCCN.

Added coverage for small bowel adenocarcinoma per NCCN.

Phesgo SGM 3986-A 2026 – Added requirement for clinical stage for adjuvant treatment per Label and NCCN. Updated verbiage from recurrent to recurrent unresectable disease to align with NCCN.

Inluriyo SGM 7208-A 2026a – Updated verbiage from ER positive to HR positive to align with NCCN

Added coverage for recurrent unresectable disease per NCCN

Updated verbiage for non-postmenopausal member to if the member is not postmenopausal, hormone suppression is being achieved through surgery, irradiation, or concomitant use with a gonadotrophin-releasing hormone agonist (GnRH) (e.g., leuprolide [Lupron]) to align with NCCN. Added criteria for regimens per NCCN.

Tecentriq 1766-A SGM 2026 – For non-small cell lung cancer, added additional contraindicated mutations, aligned use for subsequent treatment as a single agent, and specified use for adjuvant treatment for stage IB to IIIB disease, per NCCN.

For hepatocellular carcinoma, expanded coverage for progressive, unresectable, or metastatic disease, per NCCN.

For melanoma, specified use as subsequent treatment when used in combination with cobimetinib and vemurafenib, per NCCN.

Added coverage for small bowel adenocarcinoma, per NCCN.

Tecentriq Hybreza SGM 6665-A 2026 – For non-small cell lung cancer, added additional contraindicated mutations, aligned use for subsequent treatment as a single agent, and specified use for adjuvant treatment for stage IB to IIIB disease, per NCCN.

For hepatocellular carcinoma, expanded coverage for progressive, unresectable, or metastatic disease, per NCCN.

For melanoma, specified use as subsequent treatment when used in combination with cobimetinib and vemurafenib, per NCCN.

Added coverage for small bowel adenocarcinoma, per NCCN

Bizengri SGM 6755-A 2026a – For non-small cell lung cancer and pancreatic adenocarcinoma, added coverage for recurrent disease and requirement for single agent therapy per NCCN. Added coverage for biliary tract cancers per NCCN.

Imjudo SGM 5652-A 2026 – For esophageal, esophagogastric junction, and gastric cancer, updated coverage to require adenocarcinoma per NCCN.

Tukysa SGM 3782-A 2026a – For breast cancer, added coverage for use in metastatic breast cancer with HER2 activating mutation as third-line or later when used in combination with trastuzumab with or without fulvestrant. Added documentation requirement for HER2 activating mutation.

For colorectal cancer, added requirement that member has not previously received treatment with HER2 inhibitor and removed requirement for intensive therapy or progression per NCCN.

Created new section for appendiceal neoplasms and cancers per NCCN and added coverage for goblet cell adenocarcinoma and undifferentiated carcinoma not otherwise specified and added requirement that member has not received previous treatment with HER2 inhibitor per NCCN.

lapatinib-Tykerb SGM 1902-A 2026 – For breast cancer, updated to recurrent unresectable disease; removed coverage for advanced disease or disease with no response to preoperative systemic therapy for HR+/HER2+ disease; and added place in therapy as fourth line and beyond when used in combination with trastuzumab or capecitabine per NCCN.

For colorectal cancer, added requirement for primary therapy when intensive therapy not recommended and added requirement for no previous HER2 inhibitor use when used for subsequent therapy per NCCN. Added coverage for use as initial therapy for unresectable metachronous metastases per NCCN.

fulvestrant-Faslodex SGM 2903-A 2026a – Added documentation requirement for HER2 activating mutation status

For breast cancer, updated to recurrent unresectable disease and added coverage for triple negative metastatic disease with HER2 activating mutation per NCCN

For endometrial carcinoma, added coverage for use in combination with abemaciclib for ER positive disease per NCCN

Added requirement for staging for endometrial stromal sarcoma per NCCN

Nerlynx SGM 2178-A 2026 – For breast cancer, per NCCN: removed staging requirement for adjuvant treatment; updated to recurrent unresectable disease; added place of therapy as 4th line and beyond when used in combination with capecitabine; added coverage for brain metastases in combination with ado-trastuzumab per NCCN

Ixempra SGM 1897-A 2026 – For breast cancer, updated to recurrent unresectable disease and added place in therapy as fourth line and beyond when used in combination with trastuzumab per NCCN

eribulin-Halaven SGM 1893-A 2026 – For breast cancer, updated to recurrent unresectable disease and added place in therapy as fourth line and beyond when used with margetuximab and trastuzumab per NCCN

Added coverage for dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma and epithelioid hemangioendothelioma per NCCN

Verzenio SGM 2342-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer to align with NCCN.

Removed early stage requirement for adjuvant treatment of breast cancer to align with NCCN.

Added coverage for treatment of recurrent or metastatic endometrial carcinoma in combination with fulvestrant, per NCCN.

Added coverage for adjuvant treatment of endometrial carcinoma, per NCCN.

Added coverage for liposarcoma, per NCCN.

Kisqali Femara Co-Pack SGM 2104-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer to align with NCCN.

Removed early stage requirement for adjuvant treatment of breast cancer to align with NCCN.

Added coverage for adjuvant treatment of endometrial carcinoma, per NCCN.

Kisqali SGM 1639-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer to align with NCCN.

Removed early stage requirement for adjuvant treatment of breast cancer to align with NCCN.

Added coverage for adjuvant treatment of endometrial carcinoma, per NCCN.

Ibrance SGM 1726-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer to align with NCCN.

Removed retroperitoneal requirement from unresectable liposarcoma to align with NCCN.

Added coverage for retroperitoneal well-differentiated or dedifferentiated locally advanced or metastatic liposarcoma per Lexicomp.

Added coverage for endometrial carcinoma and uterine sarcoma per NCCN.

Itovebi SGM 6696-A 2026 – Updated verbiage from recurrent to recurrent unresectable breast cancer to align with NCCN.

Orserdu SGM 5770-A 2026 – For breast cancer, updated to recurrent unresectable disease per NCCN.

Piqray SGM 3089-A 2026 – For breast cancer, updated to recurrent unresectable disease per NCCN.

Truqap SGM 6252-A 2025 – For breast cancer, updated from recurrent to recurrent unresectable disease and removed specification that disease recurrence was within 12 months of adjuvant therapy per NCCN.

Cyramza SGM 1679-A 2026 – For NSCLC, added requirement for use as first-line therapy in combination with erlotinib per Label and NCCN.

For thymic carcinoma, added requirement that medication be used as first-line therapy for recurrent, advanced, or metastatic disease per NCCN.

Daurismo SGM 2793-A 2026 – Added documentation section requiring submission of IDH1 mutational status. For the treatment of acute myeloid leukemia, specified that the medication should be used for low-intensity induction treatment, per NCCN.

Xospata SGM 2807-A 2026 – Limited total duration of maintenance therapy for AML to a total of 26 months, per NCCN.

Komzifti SGM 7287-A 2026 – Removed requirement that no other satisfactory alternative treatment options are available to align with NCCN.

Added requirement that medication will be used as a single agent per NCCN.

Tibsovo SGM 2635-A 2026 – For the treatment of chondrosarcoma, specified use as a single agent, per NCCN.

For the treatment of central nervous system cancers, specified that Tibsovo may be used in members who are unable to tolerate vorasidenib, per NCCN. Added coverage for recurrent or progressive high grade gliomas, per NCCN.

Venclexta SGM 2374-A 2026 – Added coverage for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) use in combination with zanubrutinib (Brukinsa), per NCCN.

Removed coverage of use in combination with low-dose cytarabine for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) to align with NCCN.

Added coverage for refractory multiple myeloma, per Lexicomp.

Added coverage for multiple myeloma with CNS disease, per NCCN.

Added coverage for systemic light chain amyloidosis in combination with daratumumab (Darzalex) or daratumumab and hyaluronidase-fihj (Darzalex Faspro), per NCCN.

Updated coverage for B-Cell Acute Lymphoblastic Leukemia (B-ALL) to allow frontline use, per NCCN.

Added coverage for POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes) Syndrome, Monoclonal Immunoglobulin Deposition Disease (MIDD), Monoclonal Gammopathy of Renal Significance (MGRS), and Histologic (Richter) transformation to diffuse large B-cell lymphoma, per NCCN.

betaine-Cystadane SGM 2988-A 2026 – Added initial coverage criteria and documentation requirement that member exhibits clinical signs and symptoms of disease at baseline.

For homocystinuria, added documentation requirement showing homocysteine level that is undetectable or present in small amounts, or a substantial decrease in homocysteine level since initiating treatment.

For methylmalonic acidemia with homocystinuria, added documentation requirement showing benefit from therapy as evidenced by disease stability or improvement.

Pombiliti SGM 6204-A 2026 – Specified that member demonstrates a deficiency of enzyme activity 'less than 40% of normal controls' in coverage criteria and documentation per ACMG Practice Guideline.

Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

miglustat products SGM 2098-A 2026 – For Gaucher Disease type 1, added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

For Gaucher Disease type 1, added continuation criteria and documentation requirement that member is receiving benefit from therapy.

For Late-onset Pompe disease, specified that member demonstrates a deficiency of enzyme activity 'less than 40% of normal controls' per ACMG Practice Guideline.

For late-onset Pompe disease, added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

For Niemann-Pick disease, added continuation criteria that member is receiving benefit from therapy.

sapropterin products SGM 2012-A 2026 – For PKU, added requirement that diagnosis was confirmed by enzyme assay or genetic testing and added requirement that medication will be used in conjunction with a phenylalanine (Phe)-restricted diet to align with FDA label.

Aldurazyme SGM 2049-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Elaprase SGM 2052-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Mepsevii SGM 2415-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Naglazyme SGM 2056-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Vimizim SGM 2057-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Cystagon SGM 2089-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Procysbi SGM 2095-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Cerdelga SGM 2050-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Added continuation criteria and documentation requirement that member is receiving benefit from therapy.

Elelyso SGM 2053-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Added continuation criteria and documentation requirement that member is receiving benefit from therapy.

VPRIV SGM 2058-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Added continuation criteria and documentation requirement that member is receiving benefit from therapy.

Cerezyme SGM 2051-A 2026 – Added initial coverage criteria and documentation requirement that member is showing clinical signs and symptoms of disease at baseline.

Added continuation criteria and documentation requirement that member is receiving benefit from therapy.

Cystaran-Cystadrops SGM 2090-A 2026 – Added initial documentation requirement for presence of corneal cystine crystal accumulation at baseline.

Added continuation documentation requirement for corneal cystine crystal accumulation has not increased since initiating therapy.

Visudyne SGM 3011-A 2026 – Added criteria that medication must be prescribed by or in consultation with an ophthalmologist.

Alyftrek SGM 6783-A 2026a –
1) Per FDA label update: Added clinical diagnosis of cystic fibrosis. Removed cystic fibrosis transmembrane conductance regulator (CFTR) gene list. Added requirement for detection of a mutation in the CFTR gene that results in the production of CFTR protein.

2) Updated prescriber specialties to include prescribers specialized in the treatment of cystic fibrosis.

Arikayce SGM 3150-A 2026 –
1) Added documentation requirements.

2) Added prescriber specialties.

3) Added adult age requirement per FDA label.

4) Added examples of medications utilized in combination antibacterial regimens for clarity [per American Thoracic Society (ATS), European Respiratory Society (ERS), European Society of Clinical Microbiology and Infectious Diseases (ESCMID), and Infectious Diseases Society of America (IDSA) (ATS/ERS/ESCMID/IDSA) clinical practice guideline.

Gazyva SGM 2075-A 2026 – For lupus nephritis (LN): Updated initial criteria to require kidney biopsy to confirm LN per 2024 ACR Guideline for the Screening, Treatment, and Management of Lupus Nephritis. If biopsy is contraindicated, the member must be positive for SLE autoantibodies. Added hydroxychloroquine as another example of standard therapy regimen. Added age requirement for members 18 years of age or older per FDA label. Added prescriber specialities.

Increlex SGM 1740-A 2026 –
1) Expanded growth chart documentation to include chart notes or medical record documentation showing heights and growth velocities.

2) Added prescriber specialty.

Lupkynis SGM 4448-A 2026 –
1) Added prescriber specialties.

2) Added age requirement for 18 years of age or older per FDA label.

3) Updated initial criteria to require kidney biopsy to confirm lupus nephritis per 2024 ACR Guideline for the Screening, Treatment, and Management of Lupus Nephritis. If biopsy is contraindicated, the member must be positive for SLE autoantibodies.

mifepristone-Korlym 2160-A SGM 2026 –
1) Added requirement to confirm diagnosis of Cushing's syndrome/disease per the Pituitary Society guideline on diagnosis and management of Cushing's disease.

2) Added prescriber specialties.

3) Increased initial approval duration from 6 months to 12 months.

4) Added adult age requirement per FDA label.

5) Added pretreatment fasting plasma glucose and 2-hour plasma glucose as additional options for documentation of glucose intolerance.

Otezla-Otezla XR SGM 2002-A 2026 –
1) Added compendial use for moderate to severe immunotherapy-related inflammatory arthritis per NCCN.

2) Added rheumatologist as a prescriber specialty for immune checkpoint inhibitor-related toxicity.

3) For immunotherapy-related psoriasis and psoriasiform diseases, require inadequate response, intolerance or contraindications to high potency topical corticosteroids (previously medium or high) to align with NCCN guidelines.

Pulmozyme SGM 1886-A 2026 – Added prescriber specialties.

Reblozyl SGM 3407-A 2026 –
1) For prescriber specialties, separated out by indication.

2) Added coverage criteria for myelodysplastic/myeloproliferative neoplasm with SF3B1 variant and thrombocytosis (MDS/MPN-SF3B1-T).

Saphnelo SGM 4876-A 2026 –
1) Added prescriber specialties.

2) Added age requirement for 18 years of age or older per FDA label.

Tavneos SGM 5019-A 2026 –
1) Added prescriber specialties.

2) Added age requirement for members 18 years of age or older per FDA label.

Trikafta SGM 3374-A 2026a –
1) Per FDA label update: Added clinical diagnosis of cystic fibrosis. Removed cystic fibrosis transmembrane conductance regulator (CFTR) gene list. Added requirement for detection of a mutation in the CFTR gene that results in the production of CFTR protein.

2) Updated prescriber specialties to include prescribers specialized in the treatment of cystic fibrosis.

Vijoice SGM 5360-A 2026 – Added prescriber specialties.

Vykat XR SGM 6921-A 2026 – Added prescriber specialties.

dichlorphenamide-Keveyis-Ormalvi SGM 2491-A 2026 –
1) Added documentation requirements.

2) Added prescriber specialties.

3) Added serum potassium concentration requirements.

nintedanib-Ofev SGM 1882-A 2026 –
1) For idiopathic pulmonary fibrosis (IPF): Added transbronchial lung cryobiopsy (TBLC) as

another option for diagnosing IPF (usual interstitial pneumonia [UIP], probable UIP, indeterminate UIP) per the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and Latin American Thoracic Association (ATS/ERS/JRS/ALAT) guidelines. Added requirement for multidisciplinary review by an IPF experienced radiologist and pulmonologist for UIP diagnosis. Multidisciplinary review will also be required for probable UIP and indeterminate UIP (previously only required if lung biopsy was not conducted).

2) For progressive pulmonary fibrosis: Added documentation of progressive disease.

3) Added prescriber specialties.

4) Updated program name to include generic nintedanib.

pirfenidone-Esbriet SGM 1881-A 2026 –
1) For idiopathic pulmonary fibrosis (IPF): Added transbronchial lung cryobiopsy (TBLC) as another option for diagnosing IPF (usual interstitial pneumonia [UIP], probable UIP, indeterminate UIP) per the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and Latin American Thoracic Association (ATS/ERS/JRS/ALAT) guidelines. Added requirement for multidisciplinary review by an IPF experienced radiologist and pulmonologist for UIP diagnosis. Multidisciplinary review will also be required for probable UIP and indeterminate UIP (previously only required if lung biopsy was not conducted).

2) Added prescriber specialties.

tasimelteon-Hetlioz-Hetlioz LQ SGM 2426-A 2026 –
1) For Non-24-Hour Sleep Wake Disorder (Non-24): Added adult members age requirement per FDA label. Added documentation requirement for diagnosis. Increased initial approval duration from 6 months to 12 months.

2) For Smith-Magenis Syndrome (SMS): Added age requirement for 3 years of age or older per FDA label. Added genetic testing requirement for diagnosis confirmation. Increased initial approval duration from 6 months to 12 months.