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Electronic Health Record (EHR) Patient List Guide

Considerations for Identifying Appropriate Patients for Folate Receptor Alpha (FRa) Testing and mirvetuximab soravtansine-gynx Treatment Evaluation

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptoralpha ($FR\alpha$) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.

FDA=US Food and Drug Administration.

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Considerations and Limitations

The Suggested Search Criteria provide health systems with guidance to identify adult patients diagnosed with ovarian cancer who meet previously defined clinical criteria.

The considerations for the Ontada EHR system were designed to facilitate clinical decision-making in platinum-resistant ovarian cancer through identification of patients with the folate receptor-alpha (FRα) biomarker and evaluation of treatment.

These considerations were designed specifically to create a Suggested Search Criteria in the EHR system and will not work for other conditions, treatments, or therapeutic areas and are not applicable for other EHR systems.

The process outlined in this piece is variable, and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS

Ocular Disorders

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

FRa Testing

EHR SYSTEM CONSIDERATIONS

The EHR system considerations reporting solution may be used to create a search criteria. Patients with platinum-resistant ovarian cancer, who may be candidates for FR α testing, can be identified using the steps below.

Patients with ovarian cancer who may be candidates for FRa testing

- 1. Launch Practice Insights (may require access privileges)
- 2. Select Chart Explorer, then select Explorer
- 3. Create a unique name for the patient list, for example, Ovarian Cancer patient candidates for FRalpha (FRa) testing
- **4.** Add a Facet by clicking the plus (+) icon
- 5. Select the ICD code Filter
- **6.** Enter all suggested ICD-10 codes for ovarian cancer (C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8). Click the right arrow to drag codes to the Selected Values window
- **7.** Add a Facet by clicking the plus (+) icon
- 8. Select the Procedures Filter
- **9.** Enter and select the CPT® codes for FRα testing (88341, 88342) and click the right arrow to drag codes to the Selected Values window. Exclude from the guery
- **10.** Set the logic to include patients with any of the ovarian cancer ICD-10 codes and exclude patients with a procedure order for any of the FRα testing CPT® codes
- 11. Select all the desired display columns to include in the report
- 12. Click Done
- 13. Click Explore to export the results to Excel for further manipulation

Note: to further refine this list, consider adding display columns or use the available report filters, such as current medications. Consider exporting to Excel to further refine query results.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with mirvetuximab soravtansine-gynx.

Pneumonitis occurred in 10% of patients treated with mirvetuximab soravtansine-gynx, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of mirvetuximab soravtansine-gynx in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold mirvetuximab soravtansine-gynx for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue mirvetuximab soravtansine-gynx in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of mirvetuximab soravtansine-gynx with close monitoring.

 ${\tt CPT}^{\scriptsize @}\hbox{-}{\tt Current Procedural Terminology; ICD-10=International Classification of Diseases, Tenth Revision.}$

FRa Testing (Cont'd)

EHR SYSTEM CONSIDERATIONS (cont'd)

Use the steps below to access reports of FRa patients who may be eligible for testing.

Note: There are canned reports that can be leveraged in the User Dashboard. The Diagnosis Report and Patient List (with a specific problem and Lab Analytes in the chart) can be considered.

To access the reports

Diagnosis Report

- · Click on Library to add the Diagnosis Report to the User Dashboard
- · Select the ovarian cancer Diagnosis and click the double chevron icon to add it to the selected lists
- · Click Submit to run the diagnosis report. The results will display in the window
- Click the Excel icon to export to Excel

Patient List

- Launch the Patient List Search
- · Click Create List to create a new list
- Enter any desired search criteria and click Add Lab Analyte (look in the Problem field to find desired
- diagnoses/problems)
- Add additional Lab Analytes (CPT[®] codes for FRα testing [88341, 88342])
- Click Search to launch the patient guery (the list can be saved if desired)

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on the severity of PN.

FRa Testing (Cont'd)

SUGGESTED SEARCH CRITERIA

Patients with ovarian cancer who may be candidates for FRa testing

Include Diagnosis of Ovarian Cancer¹⁻³

ICD-10 code	Description		
C48.1	Malignant neoplasm of the peritoneum		
C48.2	Malignant neoplasm of peritoneum, unspecified		
C48.8	8.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum		
C56.1	Malignant neoplasm of ovary, right ovary		
C56.2	Malignant neoplasm of ovary, left ovary		
C56.3	Malignant neoplasm of bilateral ovaries		
C56.9	Malignant neoplasm of ovary, unspecified		
C57.00	Malignant neoplasm of unspecified fallopian tube		
C57.01	Malignant neoplasm of right fallopian tube		
C57.02	Malignant neoplasm of left fallopian tube		
C57.10	Malignant neoplasm of unspecified broad ligament		
C57.11	Malignant neoplasm of right broad ligament		
C57.12	Malignant neoplasm of left broad ligament		
C57.20	Malignant neoplasm of unspecified round ligament		
C57.21	Malignant neoplasm of right round ligament		
C57.22	Malignant neoplasm of left round ligament		
C57.3	Malignant neoplasm of parametrium		
C57.4	Malignant neoplasm of uterine adnexa, unspecified		
C57.8	Malignant neoplasm of overlapping sites of female genital organs		

Include Medications

Include platinum-based therapies and consider the following: Prior use of bevacizumab, cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, oral cyclophosphamide (this may be documented in the medication list and/or list of regimens. Depending on the configuration and naming conventions of the regimens, consider a manual chart review to confirm the patient is platinum resistant).

Exclude Patients With Previous FRa Testing4

Procedural type	CPT® code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Embryo-Fetal Toxicity

Based on its mechanism of action, mirvetuximab soravtansine-gynx can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with mirvetuximab soravtansine-gynx and for 7 months after the last dose.

Platinum-Resistant Ovarian Cancer Treatment Evaluation

EHR SYSTEM CONSIDERATIONS

The EHR system considerations reporting solution may be used to create a search criteria. Patients with platinum-resistant ovarian cancer can be identified using the steps below.

Patients with platinum-resistant ovarian cancer

- 1. Launch Practice Insights (may require access privileges)
- 2. Select Chart Explorer, then select Explorer
- 3. Create a unique name for the patient list, for example, Platinum-resistant ovarian cancer patients
- **4.** Add a Facet by clicking the plus (+) icon
- 5. Select the ICD code Filter
- **6.** Enter all suggested ICD-10 codes for ovarian cancer (C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8). Click the right arrow to drag codes to the Selected Values window
- 7. Add a Facet by clicking the plus (+) icon
- 8. Select the Procedures Filter
- **9.** Enter and select the CPT® codes for FRα testing (88341, 88342) and click the right arrow to drag codes to the Selected Values window. Include in the query
- 10. Add a Facet by clicking the plus (+) icon
- 11. Select the Medications Filter
- **12.** Enter and select the desired treatments (cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, oral cyclophosphamide) and click the right arrow to drag treatment to the Selected Values window.
- **13.** Set the logic to include patients with any of the ovarian cancer ICD-10 codes, include patients with a procedure order for any of the FRα testing CPT® codes, and include patients with one or more of the platinum-based treatments
- 14. Click Done
- 15. Click Explore to export the results to Excel to further refine guery results

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

Platinum-Resistant Ovarian Cancer Treatment Evaluation (Cont'd)

EHR SYSTEM CONSIDERATIONS (cont'd)

Use the steps below to access reports of platinum-resistant ovarian cancer patients.

Note: There are canned reports that can be leveraged in the User Dashboard. The Diagnosis Report and Patient List (with a specific problem and Lab Analytes in the chart) can be considered.

To access the reports

Diagnosis Report

- · Click on Library to add the Diagnosis Report to the User Dashboard
- · Select the ovarian cancer Diagnosis and click the double chevron icon to add it to the selected lists
- · Click Submit to run the diagnosis report. The results will display in the window
- Click the Excel icon to export to Excel

Patient List

- Launch the Patient List Search
- · Click Create List to create a new list
- Add the platinum-based treatments (cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, oral cyclophosphamide)
- Click Add Lab Analyte (look in the Problem field to find desired diagnoses/problems)
- Add additional Lab Analytes (CPT® codes for FRa testing [88341, 88342])
- Click Search to launch the patient query (the list can be saved if desired)

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

Platinum-Resistant Ovarian Cancer Treatment Evaluation (Cont'd)

SUGGESTED SEARCH CRITERIA

Patients With Platinum-Resistant Ovarian Cancer

Include Diagnosis of Ovarian Cancer¹⁻³

ICD-10 code	Description	
C48.1	Malignant neoplasm of the peritoneum	
C48.2	Malignant neoplasm of peritoneum, unspecified	
C48.8	C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum	
C56.1	Malignant neoplasm of ovary, right ovary	
C56.2 Malignant neoplasm of ovary, left ovary		
C56.3	Malignant neoplasm of bilateral ovaries	
C56.9	Malignant neoplasm of ovary, unspecified	
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Include Patients With Previous FRa Testing4

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IMPORTANT SAFETY INFORMATION (CONT'D) USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

Notes

- The Customers (ie, physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the considerations to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each individual EHR system vary. AbbVie shall not be
 responsible for revising the implementation considerations it provides to any Customer if that Customer modifies or
 changes its software, or the configuration of its EHR system, after such time as the implementation considerations have
 been initially provided by AbbVie
- While AbbVie tests its implementation considerations on multiple EHR systems, the considerations are not guaranteed to work for all available EHR systems and AbbVie shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and AbbVie shall have no liability thereto
- The considerations have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders, all rights reserved. Reference to Ontada products is not intended
 to imply affiliation with or sponsorship by AbbVie and/or its affiliates

Indication and Important Safety Information

INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRQ) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.

WARNINGS AND PRECAUTIONS

Ocular Disorders

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (\geq 5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution;

38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with mirvetuximab soravtansine-gynx.

Pneumonitis occurred in 10% of patients treated with mirvetuximab soravtansine-gynx, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of mirvetuximab soravtansine-gynx in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold mirvetuximab soravtansinegynx for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue mirvetuximab soravtansine-gynx in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of mirvetuximab soravtansine-gynx with close monitoring.

Indication and Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (CONT'D)

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on the severity of PN.

Embryo-Fetal Toxicity

Based on its mechanism of action, mirvetuximab soravtansine-gynx can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with mirvetuximab soravtansine-gynx and for 7 months after the last dose.

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

Hepatic Impairment

Avoid use of mirvetuximab soravtansine-gynx in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see <u>full Prescribing Information</u>, including BOXED WARNING

References: 1. ICD10 data. Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum. Accessed February 21, 2023. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C45-C49/C48.8 2. ICD 10 data. Malignant neoplasm of ovary. Accessed February 21, 2023. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C56- 3. ICD 10 data. Malignant neoplasm of other and unspecified female genital organs. Accessed February 21, 2023. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C57- 4. Mirvetuximab soravtansine-gynx. Prescribing Information. Waltham, MA: AbbVie Inc; 2024.

