### Separate Reimbursement for ORBACTIV® (oritavancin)

<table>
<thead>
<tr>
<th>Setting of Care</th>
<th>Medicare</th>
<th>Medicaid</th>
<th>Private Insurers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient</td>
<td>No</td>
<td>Varies; Typically not</td>
<td>Varies; Typically not</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>Yes</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Freestanding Infusion Centers and Physician Offices</td>
<td>Yes</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

#### Medicare

Medicare does not reimburse separately for ORBACTIV® when used in the Inpatient setting of care; rather, ORBACTIV® is reimbursed through the MS-DRG payment. Private insurers and State Medicaid agency reimbursement policies vary, but typically will not provide a separate reimbursement for ORBACTIV® in the Inpatient setting.

#### Hospital Outpatient

Medicare will reimburse the hospital for ORBACTIV® separately when used in the outpatient setting of care. Reimbursement will be processed through correct reporting of a drug specific J-Code using the corresponding units delineated in the instructions below. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for ORBACTIV® in the outpatient setting.

#### Freestanding Infusion Centers and Physician Offices

Medicare will reimburse for ORBACTIV® separately when used in freestanding infusion centers. Reimbursement will be processed through correct reporting of a drug-specific J-Code using the corresponding units delineated in the instructions below. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for ORBACTIV® in the freestanding infusion center setting.

### Quick Coding View for Medicare, Medicaid and Private Insurers

#### Hospital Inpatient

**ICD-10-CM Diagnosis Codes**

- L00.XX-L08.XX, Infections of skin and subcutaneous tissue

Additional ICD-10-CM Diagnosis Codes related to cellulitis, abscess, carbuncle, furuncle, and wound infection but outside of the range specified above may also be applicable when using ORBACTIV®. Please call 1-844-ORBACTIV for more information. Please also consult with your payor to obtain specific coverage policies and requirements for covered indications.

**ICD-10-CM Procedure Codes:** 3E03329, Introduction of other anti-infective into peripheral vein, percutaneous approach

**Common MS-DRGs**

- MS-DRG 602: Cellulitis with MCC
- MS-DRG 603: Cellulitis without MCC
- MS-DRG 862: Postoperative and Post-Traumatic infections w/MCC
- MS-DRG 863: Postoperative and Post-Traumatic infections w/o MCC

#### Hospital Outpatient

**ICD-10-CM Diagnosis Codes:** Please refer to the Inpatient section for diagnosis codes.

**ICD-10-CM Procedure Codes** do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.

**CPT Procedure Codes**

- 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- 96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour
- G0463: Hospital outpatient clinic visit for assessment and management of a patient

#### Freestanding Infusion Centers and Physician Offices

**ICD-10-CM Diagnosis Codes:** Please refer to the Inpatient section for diagnosis codes.

**ICD-10-CM Procedure Codes** do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.

**CPT Procedure Codes**

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CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MCC=major complication or commodity; MS-DRG=Medicare Severity Diagnosis-Related Group

Please see Indication and Important Safety Information on last page
### Healthcare Common Procedure Coding System (HCPCS) Codes

The following are the drug codes for appropriate billing. Medicare, private payers, and state Medicaid programs require UB-04 (CMS-1450) claim forms (for Hospital Outpatient setting) or CMS-1500 (for Freestanding Infusion Center setting) to report the following codes and amount of product used to facilitate appropriate reimbursement.

<table>
<thead>
<tr>
<th>Setting</th>
<th>HCPCS</th>
<th>Billing Description</th>
<th>2016 Medicare Payment Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Outpatient</td>
<td>J2407</td>
<td>Injection, oritavancin, 10 mg</td>
<td>ASP + 6%‡</td>
</tr>
<tr>
<td>Freestanding Infusion Centers and Physician Offices</td>
<td>J2407</td>
<td>Injection, oritavancin, 10 mg</td>
<td>ASP + 6%‡</td>
</tr>
</tbody>
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‡ Does not include impact of sequestration required by the Budget Control Act of 2011. The effective payment rate for separately covered drugs, including ORBACTIV®, is ASP + 4.3%.

The following are the billing units for ORBACTIV® (oritavancin).

<table>
<thead>
<tr>
<th>Setting</th>
<th>HCPCS</th>
<th>Billing Description</th>
<th>Billing Unit</th>
</tr>
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<tbody>
<tr>
<td>Hospital Outpatient§</td>
<td>J2407</td>
<td>Injection, oritavancin, 10 mg</td>
<td>120 units (1200 mg = 120 billing units)</td>
</tr>
<tr>
<td>Freestanding Infusion Centers and Physician Offices§</td>
<td>J2407</td>
<td>Injection, oritavancin, 10 mg</td>
<td>120 units (1200 mg = 120 billing units)</td>
</tr>
</tbody>
</table>

§ Please note: Other payors may require different billing units. Please follow payor guidance.

Accurate reporting of the ORBACTIV® HCPCS code, as well as the quantity administered to each patient, is required for appropriate reimbursement. When completing a UB-04/ CMS 1450 or CMS 1500 form for ORBACTIV®, payers may also require the following information:

- **Drug Name**: ORBACTIV® (oritavancin) for injection
- **Route of Administration**: By intravenous infusion over 3 hours
- **Quantity Administered**: 1200 mg
- **Dose of Product**: 1200 mg
- **NDC**: 65293-015-01 ORBACTIV® single use 50 mL capacity vial of lyophilized powder containing 400 mg of oritavancin
  65293-015-03 Three vials are packaged in a carton to supply for a single 1200 mg dose treatment
- **Packaging (e.g., single-dose vial)**: Three vials packaged in a carton to supply for a single 1200 mg dose treatment

Some payers may also require prescribing information, FDA-approval letter, support of medical necessity and a drug purchase invoice.

Please see Indication and Important Safety Information on last page
Valid through Q4 2016
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Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44; e.g.:
- 96366 for each additional hour of IV infusion
- 0510 for IV infusion administration in the clinic
Note: Other revenue codes may apply.

Field 44: Enter appropriate CPT/HCPCS codes and modifiers; e.g.:
- J2407 is the designated HCPCS code for patients in the hospital outpatient setting.
- 96365 for first hour of IV infusion
- 96366 for each additional hour of IV infusion

Field 46: Report the appropriate unit of service. ORBACTIV® is typically billed in the hospital outpatient setting on a “per 10 mg basis.” However, some payors may provide alternate guidance.
Example: A full course of ORBACTIV® is equal to 120 units of J2407 (1200 mg).

Field 66: Identify the type of ICD diagnosis code used; e.g. enter a “0” for ICD-10-CM.

Field 74: Enter ICD-10-CM procedure code for treatment in the hospital inpatient setting; e.g. 3E0329 Introduction of other anti-infective into peripheral vein, percutaneous approach.
Enter principal ICD-9-CM procedure code for treatment in the hospital outpatient setting; e.g. 99.21 for Injection of Antibiotic.

Field 67: Enter the appropriate diagnosis code; e.g. L00.XX-L08.XX, Infections of skin and subcutaneous tissue.
Note: Other diagnosis codes may apply.

Field 80: Enter the appropriate drug identifying information as required by payor; e.g. brand and generic name, NDC code in 11 digit format, dosage, method of administration, etc.
Note: Additional information may also be sent via attachment electronically or other format as allowed by payor.

Please see Indication and Important Safety Information on last page.
### Box 19: Additional Information
Enter the appropriate drug identifying information as required by payor; e.g. brand and generic drug name, NDC code in 11 digit format, dosage, method of administration, etc.

ORBACTIV® is only sold in cartons containing 3 vials, therefore the carton NDC ending in 03 should be utilized and billed as 1 unit.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payor.

### Box 21: Diagnosis
Enter the appropriate ICD-10-CM diagnosis code; e.g. L00.XX-L08.XX, Infections of skin and subcutaneous tissue. Final code depends on medical record documentation.

Note: Other diagnosis codes may apply.

### Box 21: ICD Indicator
Identify the type of ICD diagnosis code used; e.g. enter “0” for ICD-10-CM.

### Box 24 D: Procedures, services, or suppliers
Enter the appropriate CPT/HCPCS codes and modifiers; e.g.:
- Drug J2407 for ORBACTIV®
- 96365 First hour IV infusion
- 96366 Each additional hour IV infusion

### Box 24 G: Units
Enter the appropriate number of units of service. ORBACTIV® is typically billed in the physician office setting on a “per 10 mg basis.”

Example: A full course of ORBACTIV® is equal to 120 units of J2407 (1200 mg).

Note: Some payors may provide alternate guidance.
Disclaimer

The use of this guide is strictly for informational purposes. The information contained in this document is not intended for purposes of providing clinical practice guidelines for use of ORBACTIV®. Please see the package insert for more information.

The Medicines Company specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this sample form. The Medicines Company cannot guarantee, nor is responsible for, the payment of any claim. The coding, coverage, and payment for ORBACTIV® may vary by payer, plan, patient, and setting of care. For more information, healthcare professionals should check with individual payers for specific coding, coverage and payment requirements in the use of ORBACTIV®. It is the sole responsibility of the healthcare professional to properly code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient’s medical records.

Coding determinations and analyses should always be independently researched and assessed. Providers are responsible for selecting the most appropriate diagnosis code for a specific patient. Providers should contact a patient’s health plan, as health plans may have specific code requirements for ORBACTIV® administration.

Indication

ORBACTIV® (oritavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused or suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible [MSSA] and methicillin–resistant [MRSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only).

Important Safety Information

Contraindications
Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (5 days) after ORBACTIV® administration because the activated partial thromboplastin time (aPTT) test results are expected to remain falsely elevated for approximately 120 hours (5 days) after ORBACTIV® administration.

ORBACTIV® is contraindicated in patients with known hypersensitivity to ORBACTIV®.

Warnings and Precautions
Concomitant warfarin use: Co-administration of ORBACTIV® and warfarin may result in higher exposure of warfarin, which may increase the risk of bleeding. Use ORBACTIV® in patients on chronic warfarin therapy only when the benefits can be expected to outweigh the risk of bleeding.

Coagulation test interference: ORBACTIV® has been shown to artificially prolong aPTT for up to 120 hours, and may prolong PT and INR for up to 12 hours, ACT for up to 24 hours, and D-dimer for up to 72 hours.

Hypersensitivity reactions have been reported with the use of antibacterial agents including ORBACTIV®. Discontinue infusion if signs of acute hypersensitivity occur. Monitor closely patients with known hypersensitivity to glycopeptides.

Infusion-related reactions have been reported. Slow the rate or interrupt infusion if infusion reaction develops.

Clostridium difficile-associated colitis: Evaluate patients if diarrhea occurs.

Osteomyelitis: Institute appropriate alternate antibacterial therapy in patients with confirmed or suspected osteomyelitis.

Prescribing ORBACTIV® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions
The most common adverse reactions (≥ 3%) in patients treated with ORBACTIV® were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea.

Please see accompanying Full Prescribing Information.