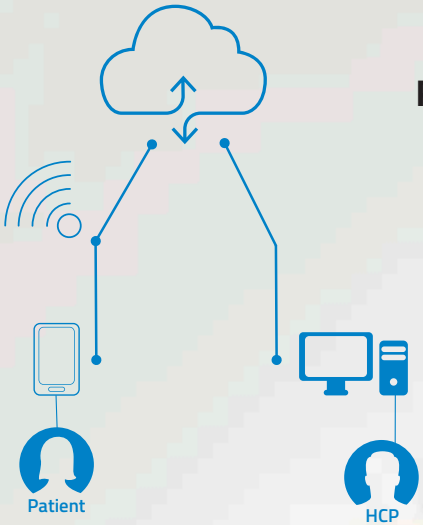
TL-HEX

TrueLok Hexapod System®



Reimbursement Guide for Remote Visibility of Orthofix TL-HEX TrueLok Hexapod System® Patients

ORTHOFIX®
ORTHOPEDICS

Introduction

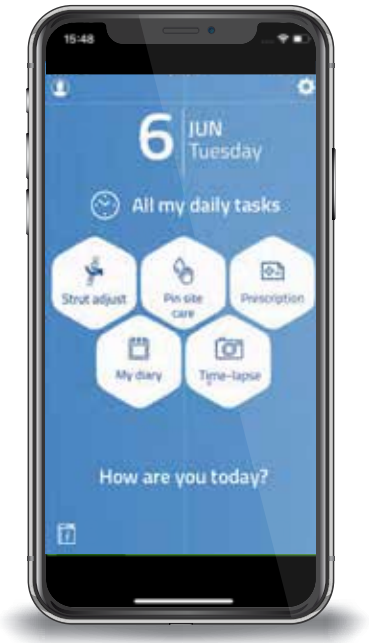
This guide is provided for informational and educational purposes only and does not reflect or represent any specific case or procedure. Providers are always responsible for accurate coding assignment based on the documented medical record. Ultimately, the provider has a better understanding of the items and services provided, the relevant settings of care, and specific payer requirements.

This information should not be construed as authoritative. What is presented here is current as of September 2020, and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payers is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. Therefore, healthcare providers must use great care and validate coding requirements ascribed by payers with whom they work. Orthofix assumes no responsibility for coding and cannot recommend codes for specific cases. When making coding decisions, we encourage you to seek input from the American

Medical Association (AMA), relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist for certain services, procedures and/or technologies, it does not guarantee payment by payers.

Orthofix Hexapodal Fixation System Overview

Orthofix TL-HEX is a dynamic, hexapodal external fixation system, approved by the U.S. Food and Drug Administration (FDA). It combines hardware and software to correct bone deformities. This hexapod-based system functions as a 3D bone segment-repositioning module. The system consists of circular and semi-circular external supports secured to the bones by wires and half pins, interconnected by six struts.



TL-HEX is used to correct bone deformities caused by a wide variety of pathologies and conditions in both children and adults.

Soon after the surgery, the patient will be shown how to adjust the length of the struts of the fixator frame, based on the prescription generated by the orthopedic surgeon with the support of the software, to achieve the planned correction. Tasks also include caring for the pin-sites, performing physical therapy exercises, and others as instructed by the orthopedic surgeon and other members of the care team.

In 2018, the myHEXplan™ mobile app was introduced as an optional accessory that acts in addition to the standard treatment management to support the TL-HEX patient from the first day after surgery, through removal of the device and all the treatment phases.

myHEXplan™
Mobile App

myHEXplan™ enriches the clinical practice of orthopedic surgeons by providing:
- A remote view of their patient's post-operative treatment actions on the mobile app;
- Patient educational and motivational support in between the scheduled check-up visits.

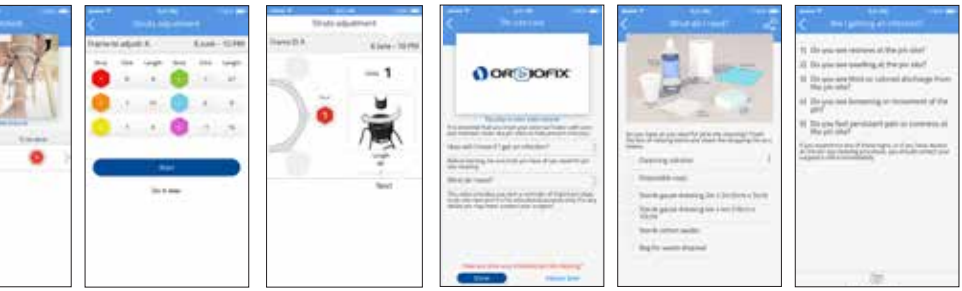
The myHEXplan™ mobile app enables TL-HEX patients to:
- Access their treatment(s) schedule on a smartphone, in addition to the paper one(s);
- Receive reminders for strut adjustments and pin-site care, and mark these activities as complete;
- Access educational materials about treatment with the TL-HEX system;
- Receive motivational messages and access other useful features such as timelapse to visualize the frame changes over time.

The myHEXplan™ mobile app is a free app that is available through the Apple App Store or Google Play Store.

myHEXplan™ for surgeon

myHEXplan™ for patient

Pin-site care



Remote Patient Monitoring Codes

As of January 1, 2018, certain Remote Patient Monitoring (RPM) services are no longer bundled into payment for other services under the Medicare Physician Fee Schedule.[1] In turn, the American Medical Association introduced new CPT[2] codes to incentivize the adoption of RPM. CMS decided to reimburse for these codes beginning January 1, 2019 under the Physician Fee Schedule.[3] Prior to this date, the only code available was CPT 99091 for the collection and interpretation of data.

CMS updated these codes with changes to RPM, officially titled "Chronic Care Remote Physiologic Monitoring," as part of the 2020 Physician Fee Schedule[3] changes.

The codes are as follows:

CPT code 99091: "Collection and interpretation of physiologic data (e.g. ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days."

> Coding Guidelines: With CPT code 99091, CMS will reimburse for professional time dedicated to monitoring services and does not require interactive communication like 99457 to bill. However, it requires a physician or other qualified health professional to perform these services, and requires 30 minutes of time every 30 days to bill. Do not report for transfer and interpretation of data from hospital or clinical laboratory or in conjunction with CPT code 99457.

CPT code 99453: "Remote monitoring of physiologic parameter(s) (e.g, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment."

> Coding Guidelines: With CPT code 99453, CMS will reimburse for the work associated with onboarding the patient to the RPM service which includes equipment setup and education to the patient.

CPT code 99454: "Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days."

> Coding Guidelines: With CPT code 99454, reimbursement is offered for providing the patient with a RPM device. This code can be billed each 30 days.

CPT code 99457: "Remote physiologic monitoring treatment management services, initial 20 minutes of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month."

> Coding Guidelines: With CPT code 99457, CMS will reimburse for clinical staff time dedicated to monitoring services and does require interactive communication (which includes phone, text and email). It requires 20 minutes of time over a calendar month; report once each 30 days, regardless of the numbers of parameters monitored. Do not report in conjunction with CPT code 99091. General supervision required.

CPT code 99458: "Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes."

> Coding Guidelines: With CPT code 99458, CMS will reimburse for clinical staff time dedicated to monitoring services with interactive communication that required an additional 20 minutes of time over a calendar month. Reported in conjunction with CPT code 99457. General supervision required.

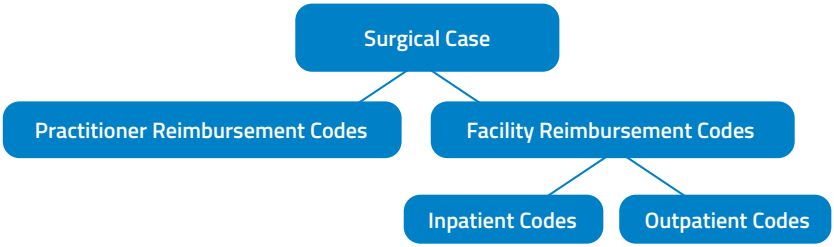
Potential Codes for Collections and Interpretation of Data from the myHEXplan™ Mobile App via the Proprietary Physician Portal

CPT Code [4-5]	CPT Description [4-5]	RVUs 2020[6]	Medicare National Average Payment 2020[6]
99091	Collection and interpretation of physiologic data (e.g. ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	1.64	$59.19
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	0.52	$18.77
99454	Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	1.73	$62.44
99457	Remote physiologic monitoring treatment management services, clinical staff/ physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes	1.43	$51.61
99458	Remote physiologic monitoring treatment management services, clinical staff/ physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	1.17	$42.22

The codes denoted are suggestions only, which reflect Orthofix's understanding of the identified sources, as prepared by our reimbursement consultants. This information should not be construed as authoritative. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payers is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Therefore healthcare providers must use great care and validate coding requirements ascribed by payers with whom they work. Orthofix assumes no responsibility for coding and cannot recommend codes for specific cases. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims.

Whenever code assignment is discussed for new or existing procedures or technologies, the different coding and reimbursement pathways and types of code sets used should be reviewed. Distinct code sets are used to report various aspects of procedures, services and technologies for reimbursement depending on the entity billing the case.

In general, reimbursement pathways and appropriate code sets take two directions resulting in two separate reimbursements for a single patient encounter when performed in a facility. Physicians report their work separately from the facility where the service is performed. This in turn creates unique coding pathways for each side of the equation that results in appropriate reimbursement from third party payers (such as Medicare or private payers).



Coding Basics

Practitioner Codes – Physician and Qualified Healthcare Provider services are reported using Current Procedural Terminology (CPT)[2] codes. These codes are created by the American Medical Association (AMA). The creation and adoption of CPT codes involves a process controlled by the AMA/CPT Editorial Panel that approves new codes and code descriptions per a set of defined standards and review process criteria.[7]

Permanent (Category I) CPT Codes – Category I codes, both existing and newly created, for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel and typically have established RVU values that can be directly used to determine reimbursement.

Temporary (Category III) CPT " T " Codes – "T" codes used for physician procedures and services that have met the qualifications outlined by the AMA/CPT Editorial Panel for temporary code status. New technologies that do not qualify for a new permanent CPT code are often assigned these "T" codes to provide a means of tracking procedures and collecting data essential to becoming a permanent CPT code.

"Unlisted" CPT Codes – "Unlisted" permanent CPT codes are used to report procedures that do not precisely fall into the description of a current CPT code per CPT/AMA guidelines. CPT coding guidelines require that CPT codes be assigned to procedures that exactly match the current use and description of a published code.

The information provided herein is intended to provide context for the service and related coding. Providers should select the service, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.

American Medical Association (AMA) Vignette of RPM Coding[7]

The official AMA vignette describes the elements of RPM CPT codes as:

Pre-Service: Pre-service includes chart review regarding patient condition and prior treatment.

Intra-Service: The intra-service period includes the physician's review, interpretation, and report of the data digitally stored and/or transmitted by the patient. The intra-service period involves at least one communication (eg, phone call or e-mail exchange) with the patient to provide medical management and monitoring recommendations.

Post-Service: The post-service period includes documenting the service in the patient's medical record and arranging for further services.

2020 CMS (Medicare) Guidelines Specific to RPM CPT Coding[3]

CMS guidelines specify:

Use with other services: CMS recognizes RPM CPT Codes as separate services from chronic care management (CCM), Transitional Care Management (TCM) and behavioral health integration (BHI) services.

> CMS is allowing RPM CPT Codes to be billed once per patient during the same service period as chronic care management (CCM) (CPT codes 99487, 99489, and 99490), Transitional Care Management (TCM) (CPT codes 99495 and 99496), and behavioral health integration (BHI) services (CPT codes 99492, 99493, 99494, and 99484).

Advance patient consent: CMS is requiring that the practitioner obtain advance beneficiary consent for the RPM service and document this in the patient's medical record.

In-person visit prior to service: For new patients or patients not seen by the billing practitioner within one year prior to billing RPM codes, CMS requires initiation of the service during a face-to-face visit with the billing practitioner, such as an Annual Wellness Visit or Initial Preventive Physical Exam, or other face-to-face visit with the billing practitioner.

General Supervision Guidelines[3]

Starting January 1, 2020, RPM services reported with CPT codes 99457 and 99458 may now be billed "incident to" under general supervision.

> General supervision, as defined by CMS, is that the service is performed under the supervisory practitioner's overall direction and control but his or her presence is not required during the performance of the procedure. General supervision does not require the physician and auxiliary personnel to be in the same building at the same time, and the physician can instead use telemedicine to exert general supervision over the auxiliary personnel.
>
> "Incident to" services are defined as services or supplies furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness. The physician or other qualified healthcare professional supervising the auxiliary personnel need not be the same individual treating the patient more broadly. However, only the supervising physician or other qualified healthcare professional may bill Medicare for "incident to" services.

Changing the RPM rules to allow "incident to" billing under general supervision greatly expands the potential operations and business models associated with RPM services, thereby allowing more patients to enjoy the quality-improving benefits of remote patient monitoring.

Global Surgery Period Guidelines[8]

Global surgery period guidelines, as published by CMS, provide:

- Global surgery guidelines may apply to procedures within the global period for the surgical provider following a surgical procedure. Specific payer guidelines differ and should be reviewed for each case.
- Follow-up visits during the post-operative period of the surgery that are related to recovery from the surgery are included in the global fee per Medicare Guidelines.
- Treatment for the underlying condition or an added course of treatment which is not part of normal recovery from surgery is not included in the global fee per Medicare Guidelines.
- All services must be supported by the documented medical record and follow specific payer guidelines.

References

1. EncoderPro for Payers Professional © 2019 Optum360, LLC. All Rights Reserved.
2. CPT Copyright 2019 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
3. 2020 MPFS Final Rule (CMS 1715F), www.cms.gov
4. CPT 2020 Professional Edition, 2019 American Medical Association (AMA); CPT is a trademark of the AMA
5. Multiple procedure reductions do not apply
6. 2020 Medicare Physician Fee Schedule RVU multiplied by conversion factor, effective January 1, 2020, www.cms.gov
7. American Medical Association Website. CPT-Current Procedural Terminology. Available at:http://www.ama- assn.org/ama/pub/physician-resources/solutions-managing-your-practice/codingbilling-insurance/cpt.page. (Accessed January 2020).
8. Medicare Learning Network – Global surgery Booklet, Access at https://www.cms.gov/Outreach and - Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalISurgerylCN907166Printfriendly.pdf

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