



NATIONAL  
OSTEOPOROSIS  
FOUNDATION

# NOF Overview of COVID-19 Activities & Issues

April 23, 2020



# Welcome & Overview

- Osteoporosis Care Challenges
- Survey Results
- CMS Response to COVID-19
  - Telemedicine
  - Medicare Part B Changes
    - Receiving Medications at Home
- Q&A

# Speakers

**Andrea J. Singer, MD, FACP, CCD**

NOF Chief Medical Officer

Director, Women's Primary Care

Director, Bone Densitometry and Fracture Liaison Service

Departments of Obstetrics and Gynecology and Medicine

MedStar Georgetown University Hospital, Washington, DC

**Saira Sultan, JD**

President & CEO

Connect 4 Strategies

Saira.sultan@connect4strategies.com

**M Kay Scanlan, JD**

Senior Advisor

Connect 4 Strategies

*Moderator:*

Claire Gill

Interim CEO

National Osteoporosis Foundation

# How is COVID-19 Affecting Patients and Practice?

- Access for patient care
  - Reduced or absent clinic schedules
  - Ability to review existing patients to determine needs and treatment plans
  - Role of telehealth
- Challenges continuing/administering injectable medications given by HCPs and infusions
  - Access to office or infusion center
  - Patient reluctance to schedule visit
  - Considerations of alternative sites, administration in patient's home
  - Reimbursement
- Access to testing
  - Temporary closure of DXA centers - need for DXA in short term
  - Necessity of labs for evaluation and treatment plans
- Challenges in identifying and evaluating new fragility fracture patients
- Geographic and Care Setting Differences

# NOF Survey of HCPs Re: COVID-19

- 81% of respondents said their practice/hospital/clinic is open to patients.
- More than 60% are offering telemedicine visits by phone or videoconference; almost 35% are offering in-office visits.
- Approximately 80% are seeing established patients; Almost 50% are seeing new patients.
- Almost 50% said they are waiting to schedule DXA exams for a later date when COVID-19 subsides.
- Over 60% said they are having difficulty getting patients appropriate osteoporosis treatment during this crisis.
  - Cause of this difficulty was cited as combination of patient fear/reluctance to make an office or hospital visit and ability to get patients the injectable medication they need.
- More than 60% are prescribing both refills and new medication.

# NOF Survey of HCPs Re: COVID-19

- Only 37% said they feel they have sufficient safe guards in place to protect patients who need to come to their office for provider-administered treatments.
- Almost half (47%) were not aware that Medicare is allowing greater flexibility in home administration of Part B medications. And more than 60% said they would be willing to use this new option for treatment of osteoporosis patients on Part B medications.
- More than 70% said they have a process in place to proactively track and contact their patients during this pandemic. And 65% said this has led to telemedicine visits.
- 43% reported it is taking more time to input into patient charts/EHRs during this crisis. And 41% said it's taking longer to follow up with patients.

# Osteoporosis Treatment Considerations During COVID-19

- For oral medications or self-injectables, patients need to check with their healthcare provider to make sure they have adequate amounts on hand:
  - Alendronate (brand names: Fosamax®, Binosto®)
  - Ibandronate (brand name: Boniva®)
  - Risedronate (brand names: Actonel®, Atelvia™)
  - Raloxifene (brand name: Evista®)
  - Calcitonin (brand names: Fortical®,
  - Estrogen (multiple brands)
  - Estrogen/Bazedoxifene (brand name Duavee®)
  - Teriparatide (brand name: Forteo®)
  - Abaloparatide (brand name: Tymlos®)
  - **For teriparatide and abaloparatide, if a patient completes the treatment course or decides to discontinue the medication, it is important that follow-on treatment is discussed to avoid bone loss upon discontinuation**
- **It is extremely important that patients taking the following medications, which are administered by a healthcare provider, stay on time for scheduled injections and discuss care plans with their providers:**
  - Denosumab (brand name Prolia®)
  - Romosozumab (brand name Evenity®)
- Zoledronic acid (brand name: Reclast®) – due to long half-life, infusions may be able to be delayed several months. Decisions should be made on a case by case basis.

# CMS Responds to the Public Health Emergency (PHE) of COVID-19

- CMS: *“We believe that this increased risk produces an immediate change, not only in the circumstances under which services can safely occur, but also results in an immediate change to the business relationships between providers, suppliers, and practitioners.”*
- CMS’ COVID-19 related initiatives are spread across various pronouncements
  - Telehealth announcements
  - Medicare IFC: March 30, 2020
  - Coronavirus Waivers & Flexibilities
  - “Blanket Waivers” and State-specific waivers for Medicaid
  - Covid-related tests and treatments
- Evolving quickly
- Effective dates as early as March 1, 2020



# Temporary Telemedicine Office Visits\*

- Medicare will temporarily pay for **any telehealth services** that otherwise would have been provided in a physician's office, clinic, or hospital.
- Medicare will not penalize physicians for use of cell phones as a telehealth mobile device and will not enforce any related HIPAA compliance regulations.
  - Cell phone is considered telemedicine platform (not telephone) since it is audio and visual capable.
  - Telemedicine visits under the IFR pay more than telephone evaluations
- New patients as well as those from other states, even if not licensed in those other states, are eligible for visits.
- Practitioners get paid for telehealth E&M as if services were in-person and can reduce or waive cost-sharing obligations for telehealth services.
- **Physician assistants, nurse practitioners can order home health services during COVID-19 emergency.**

Same payment rate as under Medicare Part B for services furnished in-person >> physician must use **Telehealth Modifier 95.**

# Fracture Liaison Service Programs

During the pandemic, FLS Programs can provide care to:

- **New** patients as well as existing patients
- Patients in **other states** – *Since FLS programs are not available in many states, this may be a critical juncture for outreach*
- Patients over ‘**cell phones**’ without risking HIPAA violations
- Patients without regard to the usual **frequency** limitations for telehealth\*\*
- Patients requiring **remote patient monitoring** services
- Patients do not have to initiate/request the office visit or telehealth visit in order for these codes to apply or for this temporary pandemic related option to be available to providers

\*\* <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

# Temporary Telemedicine Office Visits\*

## In addition to Telehealth Modifier 95 --

Code	Descriptor
<b>CPT 98966</b>	Telephone assessment and management service provided by a qualified nonphysician health care professional (5-10 minutes)
<b>CPT 98967</b>	Telephone assessment and management service provided by a qualified nonphysician health care professional (11-20 minutes)
<b>CPT 98968</b>	Telephone assessment and management service provided by a qualified nonphysician health care professional (21-30 minutes)
<b>CPT 99441</b>	Telephone evaluation and management service provided by a physician (5-10 minutes)
<b>CPT 99442</b>	Telephone evaluation and management service provided by a physician (11-20 minutes)
<b>CPT 99443</b>	Telephone evaluation and management service provided by a physician (21-30 minutes)

\*Retroactive to March 6, 2020 and will continue until the end of the public health emergency

# Telemedicine E&M (audio + visual)

E/M Code	Medical Decision Making	History	Exam	Time Spent Face to Face (avg.)
99201 (new)	Straight-forward	Problem focused	Problem focused	10 min.
99211 (established)	Straight-forward	Problem focused	Problem focused	5 min.
99202 (new)	Straight-forward	Expanded problem focused	Expanded problem focused	20 min.
99212 (established)	Straight-forward	Expanded problem focused	Expanded problem focused	10 min.
99203 (New)	Low complexity	Detailed	Detailed	30 min.
99213 (established)	Low complexity	Detailed	Detailed	15 min.
99204 (new)	Moderate complexity	Comprehensive	Comprehensive	45 min.
99214 (established)	Moderate complexity	Comprehensive	Comprehensive	25 min.
99205 (new)	High complexity	Comprehensive	Comprehensive	60 min.
99215 (established)	High complexity	Comprehensive	Comprehensive	40 min.

# Important changes to Medicare *Part B* services

- Infused/Injected osteoporosis drugs can be administered in a patient's home in two different ways

# “Home” = “doctor’s office” or hospital outpatient/clinic during the Pandemic...

Osteoporosis patients in need of the following medications can receive home-based infusion/s/injections without risking social distancing guidelines:

- Prolia™ (denosumab)
- Evenity® (romosozumab-aqqg)
- Reclast® (zoledronic acid)
- IV Boniva® (ibandronate)

Two Ways to receive your medications at home:

**#1** A physician or medical professional that has been treating patients in his/her office can provide it to the patient in their home.

- The home is “just like” the office/clinic/center where patients were getting treated;
- The physician can:
  - ✓ go to the home
  - ✓ send his/her own nurse/staff to the home (and be personally “available”), or
  - ✓ Augment his/her staff by contracting with externally resourced staff (and be “available”)

Your physician would charge the usual copay and submit the claim as usual to Medicare (for drug and administration of drug)

He/she would then pay any contracted staff used.

Reassignment?

# “Home” is more like a “pharmacy” during the Pandemic...

Osteoporosis patients in need of the following medications can receive home-based infusion/s/injections without risking social distancing guidelines:

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- IV Boniva® (ibandronate)

Two Ways to receive your medications at home:

**#2** A physician or medical professional that has been treating patients in his/her office can cite CDC guidelines on social distancing\*\* to certify a patient as “homebound.” This more relaxed definition of homebound is based on an external threat of contagion – for this pandemic and in the event of a future one.

- “Homebound” certification makes a patient eligible to get treatment from a **home health provider**.
- Unlike #1, it is a “hand-off” – the physician does not supervise or buy the drug.
- A home health provider would bring the medication and administer the infusion/injection in the home.
- This will likely “look” a lot like #1, however:
- ✓ The home health provider would bill Medicare using their own provider number ... instead of your regular physician.
- ✓ **Watch-out: A patient’s out-of-pocket costs may increase since drugs administered by Home Health fall under Part D.**

\*\* <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html>

## *Home Health Coverage*

- There are limited instances where a covered Part B osteoporosis drug can be administered by a home health provider and retain coverage for the drug under Part B. To qualify, the physician must certify that all of the following criteria are met:
  - The patient meets the criteria for the Medicare home health benefit;
  - The patient has a bone fracture related to post-menopausal osteoporosis;
  - The patient cannot self-inject the drug and is unable to learn how to self-inject the drug; and
  - There is no family member or caregiver willing and able to inject the medication.
- The NOF is seeking a clarification from CMS that would enable providers to cite to the FDA label of Part B drugs indicated for clinician administration in lieu of certifying that self-administration or injection from a care partner is not possible.



## Ask Your Patient....

Both options may “look” the same to the patient – i.e., a visiting nurse arrives at their home for an injection/infusion,

Please ask/notify the patient that if you choose Path #2 --

- This may increase the patient’s out of pocket costs;
- Make them aware of any additional patient assistance to cover higher OOP costs;
- Consider implementing Path #1 if feasible
  - Doctor can talk to the specialty pharmacy, or other distribution channel about implementation options
  - Doctor can also talk to a home infusion company, home care entity, nurse staffing agency, etc., to contract with his/her office separately

This temporary change is meant to provide patients and their clinicians flexibility, not mandate new out-of- pocket costs for patients.

**The National Osteoporosis Foundation strongly recommends that doctors carefully consider/discuss with their patients if remaining on Medicare Part B is an option because it *may be* more expensive for injectables/infusions through Medicare Part D.**

***NOF advocated for these changes, and supports CMS for the quick action taken to support Medicare patients through this pandemic.***

- For more resources on osteoporosis, visit [nof.org](http://nof.org) or BoneSource [www.bonesource.org](http://www.bonesource.org)
- For more information on medications discussed today, visit
  - Alendronate (brand names: Fosamax®): [https://www.merck.com/product/usa/pi\\_circulars/f/fosamax/fosamax\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/f/fosamax/fosamax_pi.pdf)
  - Alendronate (brand names: Binosto®): <https://www.binosto.com/>
  - Ibandronate (brand name: Boniva®): [www.gene.com/medical-professionals/medicines/boniva-injection](http://www.gene.com/medical-professionals/medicines/boniva-injection)
  - Risedronate (brand names: Actonel®, Atelvia™): <https://www.mylan.com/en/products/product-catalog/product-profile-page?id=8351da81-7fe6-48b7-964a-f3411b55a3b4>
  - Raloxifene (brand name: Evista®): <https://www.lillymedical.com/en-us/bone/evista>
  - Estrogen/Bazedoxifene (brand name Duavee®): <https://www.duavee.com/>
  - Teriparatide (brand name: Forteo®): <https://www.forteo.com/>
  - Evenity®, Prolia™: [www.amgenmedinfo.com/Home](http://www.amgenmedinfo.com/Home)
  - Reclast®: [www.medinfo.novartispharmaceuticals.com/](http://www.medinfo.novartispharmaceuticals.com/)
  - Abaloparatide (Tymlos®): [www.tymlos.com](http://www.tymlos.com)

A stylized graphic of a human figure with a circular head and radiating lines, set against a light blue background with a gradient. The figure is composed of light blue shapes, including a circle for the head and several curved lines for the arms and torso.

***NOF is preparing comments to CMS about any changes needed to allow physicians to implement the flexibility provided by the agency....and to alert/ask CMS staff to address the OOP differential for patients.***

**Contact [education@nof.org](mailto:education@nof.org) with your comments by Friday, April 24th.**

# Questions

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# CMS Resources

- The Interim Final Rule and waivers can be found at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>
- A complete list of all Medicare telehealth services can be found here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>

Remember to fill out survey....

As NOF develops its comments to CMS, please notify us of any technical or other issues you believe need to be conveyed to CMS.

# Thank You!

If you have any questions, contact [education@nof.org](mailto:education@nof.org)