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Session T209

Medicare, Clinical Trials, & You

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Objectives

- Describe the principles of the Medicare program
- Describe and discuss Medicare's clinical trial policy
- Describe and discuss Medicare's coverage of category A and B investigational device exemptions (IDE) in the context of a clinical trial
- Describe and discuss Coverage with Evidence Development (CED)
- Discuss the role of Clinicaltrials.gov
- Describe the link between Medicare and Clinicaltrials.gov
- Identify risks associated with non-compliance

Medicare…Then & Now

1965— Congress passed legislation establishing the Medicare program as Title XVIII and Title XIX of the Social Security Act in response to specific medical care needs of the elderly

1973— Coverage expanded for certain disabled persons and certain persons with kidney disease

2000— Clinical trial policy, prior to this national coverage determination Medicare beneficiaries could not participate in clinical trials- as Medicare would not cover the costs of routine care

Then - Two parts:

- Hospital insurance (HI aka Part A)
- Supplementary medical insurance (SMI aka Part B)

Now - Four parts:

- Part A (hospital coverage)
- Part B (medical Insurance)
- Part C *aka* Medicare Advantage Plans (combines A, B, and perhaps D into an HMO or PPO with a private insurer)
- Part D (prescription drug coverage)

Medicare and Its Alphabetical Parts

- **Medicare Part A—**Hospital Insurance
  - Free for Medicare beneficiaries
  - *Covers:* hospital services, skilled nursing facility care, hospice and home healthcare services

- **Medicare Part B—**Supplementary Medical Insurance
  - Premium
  - *Covers:* physician and surgeon professional fees, NP, PA (etc.) fees, some preventative care services and screening tests, ER visits, outpatient treatments

Medicare and Its Alphabetical Parts (cont)

- **Medicare Part C:** Medicare Advantage Plan (was Medicare + Choice)
  - Expands beneficiaries' options to participate in private-sector health care plans
  - A type of Medicare health plan offered by a private company that contracts with Medicare to provide you with all your Medicare part A and part B benefits
  - Medicare Advantage Plans include health maintenance organizations, preferred provider organizations, private fee-for-service plans, special needs plans, and Medicare medical savings account plans
  - If you're enrolled in a Medicare Advantage Plan, Medicare services are covered through the plan and are not paid for under original Medicare
  - Most Medicare Advantage Plans offer prescription drug (Part D) coverage AND
    - **Will** cover routine costs of device studies
    - **Will not** cover routine costs of drug/IND studies—go to original Medicare

- **Medicare Part D:** Fee and different plans. Goal is to subsidize prescription costs not covered in Medicare part A or part B. Has a coverage gap.

How Is Medicare Funded?

- The two parts of traditional Medicare are funded in very different ways
  - Part A, which covers in-patient hospital bills, is financed by a trust fund known as the Hospital Insurance Fund (HI Fund)
    - **The percent the government deducts from your paycheck—and also from your employer—is placed in the HI Fund to cover part A services**
    - **This payroll tax provides the bulk of the money that flows into the HI fund, which is in turn used to cover part A expenses**
  - Part B, which covers doctor appointments, is run by a separate trust fund, called the Supplemental Medical Insurance Trust Fund (SMI Fund)
    - Enrollee premiums and funds from the general budget supply the SMI Fund, which then pays for part B services

Medicare Is Managed by…

- Centers for Medicare & Medicaid Services (CMS) responsible for administering these programs
  - Formerly Health Care Financing Administration (HCFA)
- Payment for services by providers/hospital are under the prospective payment system (PPS)
- Payment for clinical labs and ambulance services under fee schedules
- Contract entities—Medicare Administrative Contractors (MACs)—process claims and provide payments

Medicare Administrative Contractor (MAC)

- Private healthcare insurer that has been awarded a geographic jurisdiction to process Medicare part A & part B medical claims, durable medical equipment (DME) claims, and Medicare fee-for-service beneficiaries (FFS)
- CMS relies heavily on the MACs to serve as operational contact between the Medicare FFS program and healthcare providers enrolled in the program
- Currently there are 12 part A & B MACs

National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

Underlying theme… is the item or service **reasonable and necessary;** provided for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body party…(and falls under a Medicare benefit category)

- National coverage determinations (NCDs) are statutes: they define what is covered by Medicare
- Local coverage determination (LCD)—aka local medical review policy (LMRP)—is a decision by a Medicare contract administrator (MAC) on whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Social Security Act
  - Determination as to whether the service or item is reasonable and necessary
  - LCDs are developed when there is no NCD or when there is a need to further define a NCD
  - LCDs cannot conflict with NCDs

How Medicare Works With Other Insurance

Medicare Secondary Payer Rule/Coordination of Benefits

- The primary payer pays first up to the limits of coverage
  - The secondary payer pays costs the primary insurer did not cover
- CMS determines the order of payment:
  - Medicare tries to be the secondary payer
  - Complications/injuries arising out of clinical trials: In terms of subject injury language in a contract…if a sponsor offers to pay, **Medicare holds them out as a liability insurance plan, and the sponsor has reporting requirements and COB**

Underlying Theme… Medical Necessity

- Medicare's definition of medical necessity stems from the SSA of 1965 (1862[a][1][A]) states **no payment** under Medicare part A or part B for any expenses incurred for items or services which, except for certain named exceptions…

  "are not ***reasonable and necessary*** for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part"

- **Not medically necessary:** a particular service is not a benefit under the defined benefit, for this diagnosis, **at this time** (Article for Medical Necessity – A3369- WPS, 2/1/02)

Medicare's Logic on Coverage

- According to Medicare—coverage is limited to items and services that are reasonable and necessary for the diagnosis and treatment of an illness or injury (and within the scope of a Medicare benefit category and not statutorily excluded)
- Routine costs are not standard of care

Not Medically Necessary

In other words… when Medicare does not pay, it does not mean the service should not be ordered or performed, nor does it mean it is not "standard of care"—it simply means Medicare does not pay

What Is the Difference Between Medicare & Medicaid & Private/Commercial Insurance?

- Medicare—federally funded
- Medicaid—funded federally and by the state
- Private/commercial insurance—not funded by the government

Medicare and Clinical Trials—What Does This Mean?

- There are three regulations that address Medicare coverage of clinical trials:
  - Coverage related to investigational device exemption (IDE) studies: https://www.cms.gov/Medicare/Coverage/IDE/index.html
  - Clinical trial policy: National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.htm
  - Coverage with evidence development (CED): CMS, as part of the national coverage determination (NCD), may determine coverage of an item or service only in the context of a clinical study, which typically also involves a registry
    - The NCD requiring CED are listed at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html

Clinical Trial Billing Errors = Compliance Risks

- Billing Medicare for items and services provided by the sponsor
- Billing Medicare for items and services that are for research purposes only
- Billing for items and services that are promised for free in the informed consent
- Billing for items and services for a study that is not a qualifying clinical trial

Coverage With Evidence Development

- CMS released an updated guidance document on November 20, 2014, that describes coverage with evidence development (CED)
  - CMS, as part of the National Coverage Determination (NCD), may determine coverage of an item or service only in the context of a clinical study

Centers for Medicare & Medicaid Services—Investigational Device Exemption (IDE)

- Finalized changes to IDE regulations in 2015—centralized approval of devices and changed MAC review and approval of IDEs
  - May still need to submit what routine items and services will be billed for MAC approval
- **Category A:** (experimental) will allow coverage of routine care items and service furnished in the study, but not of the category A device, which is statutorily excluded from coverage
- **Category B:** (non-experimental/investigational) IDE study will allow coverage of the category B device and routine items and services in the trial

Approved IDE studies: 316

Medicare Registration of IDEs

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FEED

Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

Approved IDE Studies

Approved IDE Studies

The following IDE studies have met CMS' standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.

Show entries: 10

Filter On:

Study Title	Sponsor Name	NCT Number	IDE Number	CMS Approval Date	Category
Safety and Effectiveness of TactiCath™ Contact Force, Sensor Enabled™ (TactiCath SE) Catheter for Ablation of Drug Refractory, Symptomatic, Persistent Atrial Fibrillation (PERSIST-END IDE)	St. Jude Medical	NCT03650556	G180149	2018-10-12	B
High-Frequency Nerve Block for Post-Amputation Pain: A Pivotal Study	Neuros Medical, Inc.	NCT02221934	G130203	2018-10-12	B
Proposed Single Center Investigational Device Exemption: Feasibility of Endovascular Repair of Ascending Aortic	Baylor Research	NCT03322033	G170196	2018-10-12	B

Medicare Coverage ~ Clinical Trials | Final National Coverage Decision (NCD) for Routine Costs in Clinical Trials (310.1) | Clinical Trials Policy (CTP)

- Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as **reasonable and necessary** items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

- Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except…

NCD for Routine Costs in Clinical Trials (310.1) —Clinical Trials Policy (CTP) (Cont)

Not considered routine cost:

- The investigational item or service, itself *unless otherwise covered outside of the clinical trial;*
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

NCD for Routine Costs in Clinical Trials (310.1) —Clinical Trials Policy (CTP) (Cont)

THREE requirements:

- The subject or purpose of trial must be an evaluation of an item or service that falls within a Medicare benefit category and is not statutorily prohibited
- The trial must not be designed exclusively to test toxicity or disease pathophysiology—it must have therapeutic intent
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteer; trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

Deemed to be automatically qualified are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD, and VA
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)…until qualifying criteria are developed and certification process established

NCD for Routine Costs in Clinical Trials (310.1) —Clinical Trials Policy (CTP) (Cont)

The Desirable Characteristic Test

- A clinical trial is a "qualifying clinical trial" if it has all 7 "desirable characteristics":
  - The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
  - The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
  - The trial does not unjustifiably duplicate existing studies;
  - The trial design is appropriate to answer the research question being asked in the trial;
  - The trial is sponsored by a credible organization or individual capable of executing the proposed trial successful;
  - The trial is in compliance with federal regulations relating to the protection of human subjects; and
  - All aspects of the trial are conducted according to the appropriate standards of scientific integrity

Method to Work With Medicare & Clinical Trial

A Billing/Coverage Analysis Provides:

- Detailed review of the study
- Detailed review of who is paying for what item or service
- Detailed review and analysis of NCDs and LCDs
- Prevents financial surprises during a project
- Provides a template for budget development (if applicable)
- Provides a tool for audits
- Provides a template to "cure" errors
- A consistent methodology for research billing
- A guide for the IRB to review the cost section of informed consent (21 CFR 50.25/ 45 CFR 46.116)
- Provides a template of subjects' financial liability for the ICF

Creating a Billing Grid/Matrix

	Screening	Randomization	Week 1	Week 2	Week 3
Informed consent	X				
Inclusion/ exclusion	X	X			
Exam	X		X	X	X
CBC	X		X	X	X
EKG	X		X		X
CT scan	X				X
Study drug		X	X	X	

Sample of Coding

	Screening	Randomization	Wk 1	Wk 2	Wk 3
Informed consent	E				
PT/PTT	S		S		
Exam	PS	PS	PS	N	N
CBC/chem panel	PS	S	N	N	N
CT scan	S		S		S
Hep B screen	S				
Rituxan			N	N	

Coverage Analysis

IRB Number#		**PAF#**	
NCT Number: NCT01958000			
Documents reviewed: Protocol, 9/20/13, Informed Consent, Draft Budget, Letter from Sponsor with IND number			
FDA Assigned IND number: 110,000		Pending Submission	
FDA Assigned IDE number:		N/A	
Is study a qualifying clinical trial under Medicare's Clinical Trial Policy?		Yes	
CT or MRI (chest, abd, pelvis) Whole body scan)	PS at screening,	L28516	See section 7.2 of study (CT or MRI (chest, abd, pelvis mandated) as is whole body bone scan)
PET Scan (whole body scan)	PS at screening	220.6	
PFT's	PS at screening	LCD L32762 (Novitas Soln)	No LCD in IL. This is not a screening test approved for coverage by Medicare; therefore in order to obtain coverage, the patient has to be symptomatic and the PI has to document medical necessity.
CT or MRI (chest, abd, pelvis) For subjects receiving study medications	N		Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer, PI to document medical necessity
PT or INR/ APTT	CL	NCD 190.16/190.17	Medicare has specific guidelines for indication

Informed Consent

- What is promised for “at no charge” to the subject = free
- 45 CFR 46.116 and 21 CFR 50.25
  - For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- Any additional costs to the subject that may result from participation in the research

Budget Development and Negotiations

Sponsor

- Contact with Medicare to register determination if IDE is a category A or category B; then register IDE with Medicare
- Budget developed for entire project
- Site specific typically for region and urban sites
- May only cover investigational services and/or services not considered SOC
- May tell site—"just bill" it is always covered
- May or may not cover costs associated with subject injury
- May want to cover co-pays or deductible
- May provide payment for insurance denials only—and request proof of denial
- May want to willing to pay for one-off costs for a particular subject or subject population

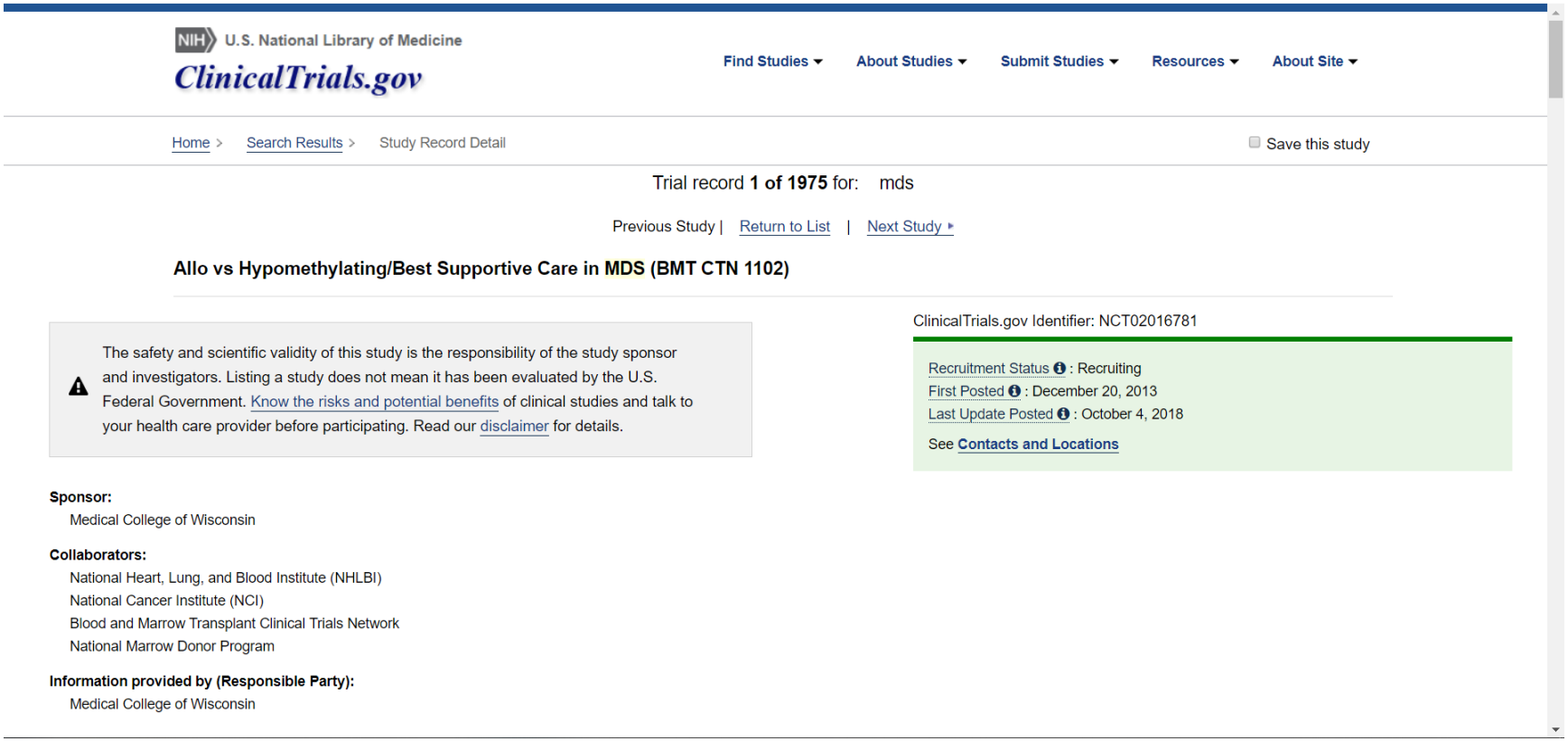
Site

- Budget should be developed based on Medicare coverage analysis
- Should include charge master rates or research rates; and for SAVVY sites, all other costs related to the conduct of a clinical trial
- Typically includes overhead
- Site specific by MAC
- Medicare covers routine care—this is not SOC
- Should not accept coverage for co-pays and deductible
- Probably not a good idea to bill for denials
- Should not provide an item or service free to one subject and bill all others
- Subject to Medicare rules and of course—responsible for billing errors

Ticklers

- Sponsor to provide device at no-cost; institution agrees to submit claims to third party payors=**?**
- Sponsor shall pay for all reasonable medical expenses incurred for the necessary medical treatment of such injury which are not covered by subject's medical or hospital insurance or other governmental programs providing such service=**?**
- Anything that addresses Medicare/Medicaid or other governmental healthcare insurance=**?**

ClinicalTrials.gov



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Trial record **1 of 1975** for: mds

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Allo vs Hypomethylating/Best Supportive Care in MDS (BMT CTN 1102)

ClinicalTrials.gov Identifier: NCT02016781

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Recruitment Status : Recruiting
First Posted : December 20, 2013
Last Update Posted : October 4, 2018

See Contacts and Locations

Sponsor:
Medical College of Wisconsin

Collaborators:
National Heart, Lung, and Blood Institute (NHLBI)
National Cancer Institute (NCI)
Blood and Marrow Transplant Clinical Trials Network
National Marrow Donor Program

Information provided by (Responsible Party):
Medical College of Wisconsin

Why Register?

- It is the law
- NIH funding is dependent on registration
- International Committee of Medical Journal Editors (ICMJE) requires registration for publication
- It is a requirement if you bill items or services to Medicare following the clinical trial policy
  (National Coverage Determination for Routine Costs in Clinical Trials [310.1])

Advanced Beneficiary Notice/BNI

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Beneficiary Notices Initiative (BNI)

- FFS ABN
- FFS HHCCN
- FFS SNFABN and SNF Denial Letters
- FFS HINNs
- FFS ED Notices
- MA Denial Notices
- MA ED Notices
- Hospital Discharge Appeal Notices
- FFS NEMB SNF
- Statutory Guidance

Beneficiary Notices Initiative (BNI)

Please Note: For Medicare Prescription Drug Coverage Notices -- see below under "Related Links."

Beneficiary Notices Initiative

Both Medicare beneficiaries and providers have certain rights and protections related to financial liability under the Fee-for-Service (FFS) Medicare and the Medicare Advantage (MA) Programs. These financial liability and appeal rights and protections are communicated to beneficiaries through notices given by providers.

Use the navigation tool on the left side of this page to link to the following financial liability notices and their instructions:

- FFS Advance Beneficiary Notice of Noncoverage (FFS ABN)
- FFS Home Health Change of Care Notice (FFS HHCCN)
- FFS Skilled Nursing Facility Advance Beneficiary Notice (FFS SNFABN) and SNF Denial Letters
- FFS Hospital-Issued Notices of Noncoverage (FFS HINNs)
- FFS Expedited Determination Notices for Home Health Agencies, Skilled Nursing Facility, Hospice and Comprehensive Outpatient Rehabilitation Facility (FFS ED Notices)

NOTE: NEW GUIDANCE IS AVAILABLE FOR THE FFS EXPEDITED DETERMINATION PROCESS. SEE "RELATED LINK" BELOW TITLED "TRANSMITTAL 2711 - EXPEDITED DET (EFF AUG 26, 2013)".

- MA Denial Notices (MA Denial Notices)
- MA Notice of Discharge and Medicare Appeal Rights (MA NODMAR)
- MA Expedited Determination Notices (MA ED Notices)
- Important Message from Medicare (IM) and Detailed Notice of Discharge (DND) (Hospital Discharge Appeal Notices)
- FFS Notice of Exclusion from Medicare Benefits - Skilled Nursing Facility (FFS NEMB SNF)

Related Links

Prescription Drug Coverage - General Information
Creditable Coverage
Transmittal 2711 - Expedited Det (Eff Aug 26, 2013)

Page last Modified: 10/11/2014 11:09 PM
Help with File Formats and Plug-Ins

Resources

- Medicare Coverage Related to Investigational Device Exemption (IDE) Studies
- https://www.cms.gov/Medicare/Coverage/IDE/index.html
- https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
- https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html
- https://clinicaltrials.gov/ct2/manage-recs

Thank you!

Questions?

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