Bridging Regions, Aligning Stakeholders: Advancing Coordinated Care in Transthyretin Amyloidosis Cardiomyopathy (ATTR-CM)

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This activity is supported by an independent medical education grant from Alnylam U.S., Inc.

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Learning Objectives

1. Discuss recent and emerging pharmacologic therapies and evidence updates in the management of transthyretin amyloidosis cardiomyopathy (ATTR-CM).
2. Describe the roles and perspectives of diverse stakeholders — including clinicians, payers, health systems, and patient representatives — in improving coordination and outcomes in ATTR-CM care.
3. Examine regional variations in access, diagnosis, and care coordination for patients with ATTR-CM to identify strategies for optimized managed care collaboration.

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Faculty

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Transthyretin Amyloidosis

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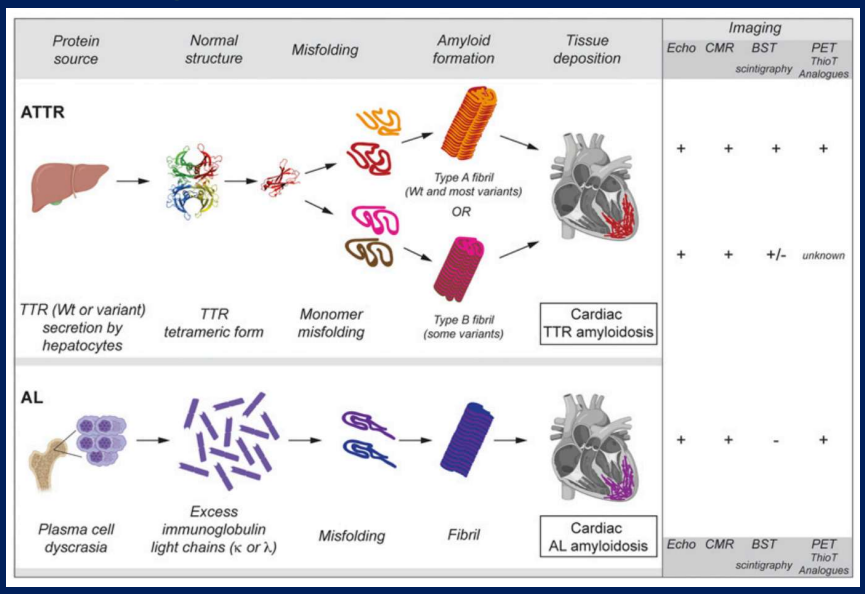
Cardiac Amyloidosis



Masri A, et al. *J Nuc Med.* Jul 2020, 61 (7) 965-970; DOI: 10.2967/jnumed.120.245381

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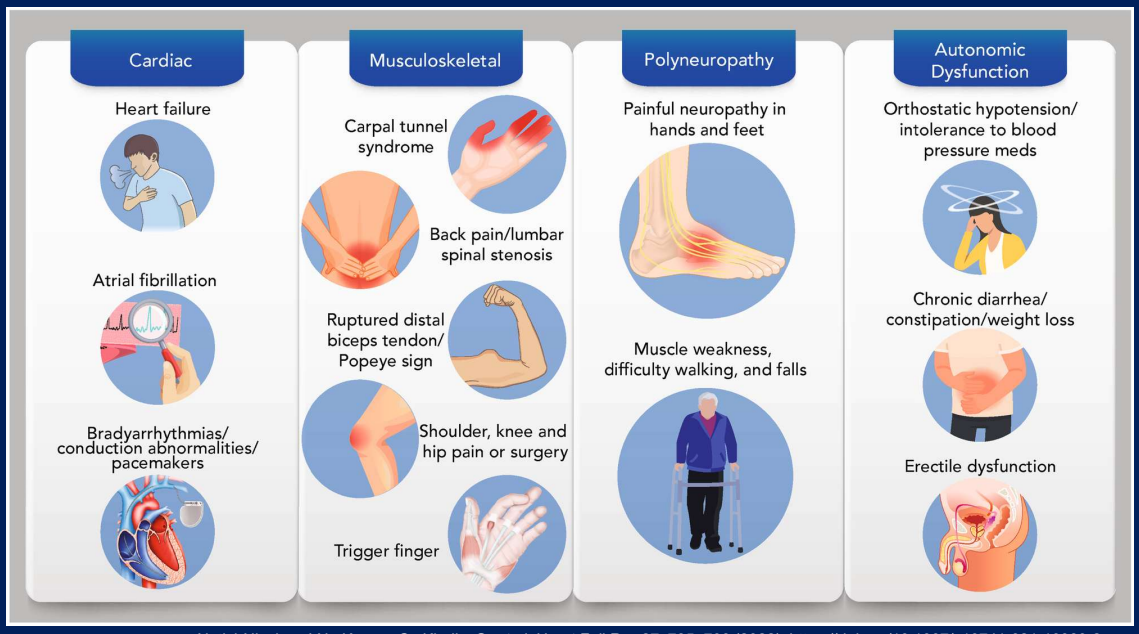

Nativi-Nicolau, J.N., Karam, C., Khella, S. *et al. Heart Fail Rev* **27**, 785–793 (2022). https://doi.org/10.1007/s10741-021-10080-2.
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Think Amyloidosis – Practical Recommendations

- Carpal tunnel syndrome in patients > 60 years of age
  - Atraumatic, not related to rheumatological condition or ongoing occupational exposure
  - Especially when bilateral
- Coexistent unexplained neuropathy
- Heart failure with any of the following:
  - Autonomic dysfunction features
  - Any unexplained increase in LV wall thickness (LV wall >/= 12 mm)
  - Abnormal LV voltage/mass ratio (or simply slightly thick LV, and low voltage limb leads)
  - Discordant NT-proBNP and volume overload/outpatient NYHA
  - Improved blood pressure control
  - Black patients (V122I)
- Calcific aortic stenosis with ≥ 1.3-1.4 cm LV (not bicuspid or rheumatic)
  - Higher risk with more LVH, conduction disease, LFLG
- Use strain in all LVH (IVS ≥ 1.2 cm)
  - Do PYP/HDP in most nHCM > 65 years of age

Nativi-Nicolau, J.N., Karam, C., Khella, S. *et al. Heart Fail Rev* **27**, 785–793 (2022). https://doi.org/10.1007/s10741-021-10080-2.

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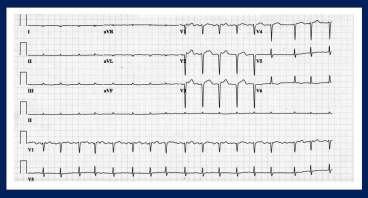
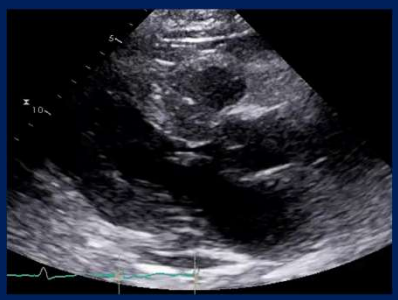
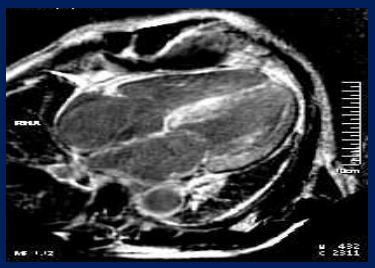
Traditional Approach

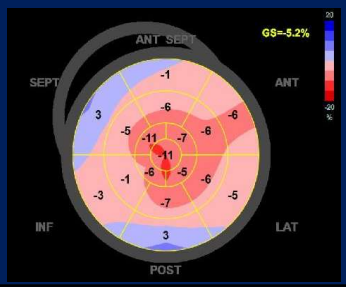






Low voltage 50% in AL

Low voltage 25% in ATTR



Images courtesy of Ahmad Masri

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Technetium pyrophosphate scintigraphy (Tc-PYP) DPD/H(M)DP

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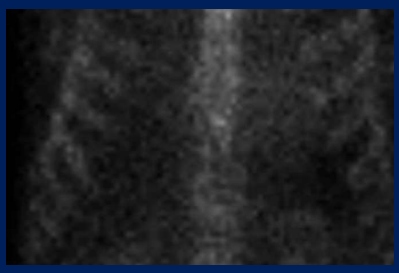
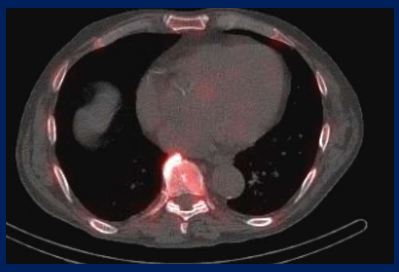
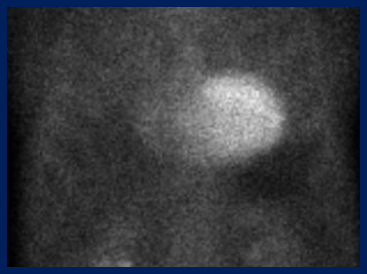
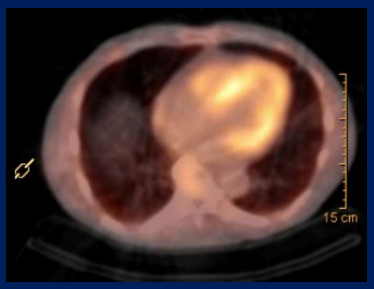
Negative scan





Positive scan





Images courtesy of Ahmad Masri

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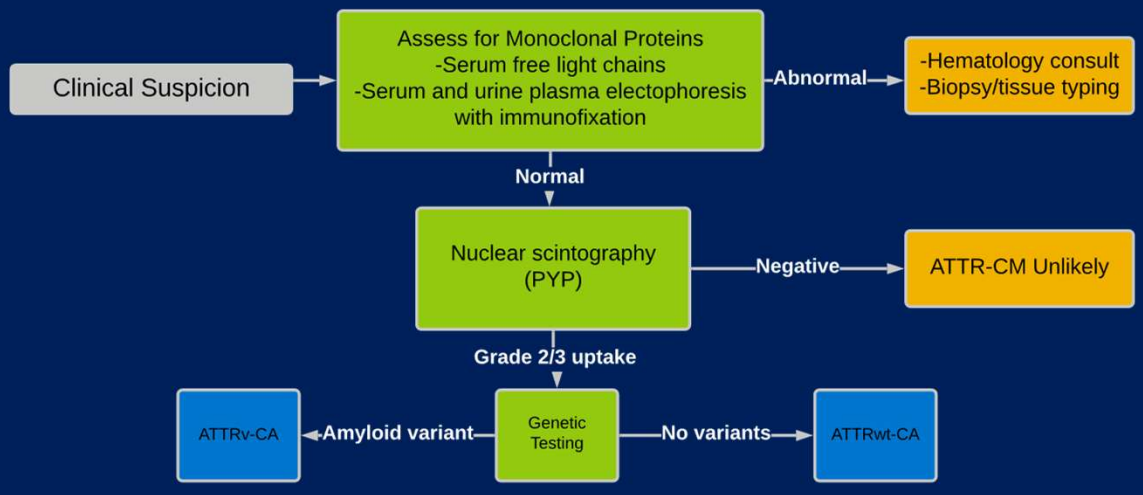
Diagnosis of Suspected ATTR-CM



ATTRv-CA, variant transthyretin cardiac amyloidisis; ATTRwt-CA, wild-type transthyretin cardiac amyloidisis. Ruberg, FL. *JAMA*. 2024 Mar 5;331(9):778-791.

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Diagnostic Pathways

Think Amyloidosis (unexplained LVH, proteinuria, worsening hypotension (or new normal BP), orthopedic red flags (carpal tunnel, biceps rupture, spinal stenosis), unexplained neuropathy)

1) Rule out Light Chain Amyloidosis (serum and urine immunofixation/immunotyping, serum free light chains)

2) Bone scintigraphy (PYP or HDP)

Kittleson et al. JACC 2025

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New and Novel Treatment Advances for ATTR-CM

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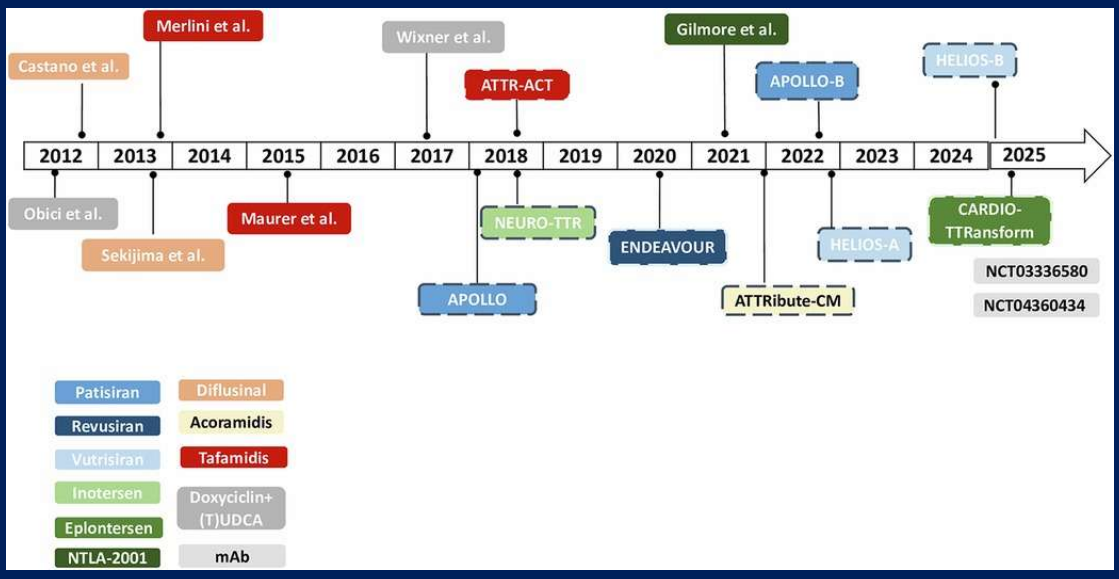

Tomasoni D, et al. *Front Cardiovasc Med*. 2023;10:1154594. https://pmc.ncbi.nlm.nih.gov/articles/PMC10242061/figure/F2/; Reprinted with permission: https://creativecommons.org/licenses/by/4.0/

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Disease-Targeted Therapies

Silencers	Stabilizers	Disrupters
Inhibit hepatic synthesis of TTR	Prevent TTR misfolding	Increases clearance of amyloid fibrils from tissues
Eplontersen, Patisiran, Vutrisiran*	Acoramadis*, Diflunisal, Tafamidis*	Doxycycline TUDCA

*FDA approved for ATTR-CM

Kittleson MM, et al. *Circulation*. 2020 Jul 7;142(1):e7-e22.
Gillmore JD, et al. *N Engl J Med*. 2024;390(2):132-142.
Fontana M, et al. *N Engl J Med* 2025;392:33-4. Maurer MS, et al. *N Engl J Med*. 2018;379(11):1007-1016;
Maurer MS, et al. *N Engl J Med* 2023;389:1553-1565; Siddiqi OK, et al. *Amyloid*. 2022;29(2):71–78.

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Comparing Phase 3 ATTR-CM Trials

ATTR-CM (wild-type or variant)

Trial Criteria	ATTRACT-CM (Tafamidis)	ATTRibute-CM (Acoramidis)	HELIOS-B (Vutrisiran)
Tafamidis use	N/A	Only allowed after 12 months	40% at baseline
NYHA Class	I-III symptoms	I-III symptoms	I-III symptoms Excluded NYHA III at high risk
6MWD	≥100 m	≥150 m	≥150 m
NT-proBNP	≥600 pg/mL	≥300 pg/mL, ≤8500 pg/mL	>300 pg/mL, <8500 pg/mL (>600 pg/mL, <8500 pg/mL in AF)
Primary End Point	Hierarchical composite all-cause death and CV hospitalizations at 30 months	Hierarchical composite all-cause death, CV hospitalizations, ΔNT-proBNP, Δ6MWD at 30 months	Composite all-cause death and recurrent CV events over 36 months

NT-proBNP, N-terminal pro-B-type natriuretic peptide; AF, atrial fibrillation; NYHA, New York Heart Association; 6MWD, 6-minute walk distance.
Hellenbart EL et al. Pharmacotherapy. 2024;45(2):124-144; Maurer MS et al. N Engl J Med. 2018;379(11):1007-1016; Gillmore JD et al. N Engl J Med. 2024;390(2):132-142; Fontana M et al. N Engl J Med. 2025;392(1):33-44.

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Comparing Phase 3 ATTR-CM Trials

Baseline Characteristic	ATTR-ACT (Tafamidis)	ATTRibute-CM (Acoramidis)	HELIOS-B (Vutrisiran)
Age, years (median)	74	77	77
NYHA class, % **I** **II** **III**	 8 60 32	 11 72 17	 13 78 9
6MWD, m (mean)	353	348	375
NT-proBNP, pg/mL (median)	3161	2306	1813
ATTRv (%)	24	10	12

NT-proBNP, N-terminal pro-B-type natriuretic peptide; AF, atrial fibrillation; NYHA, New York Heart Association; 6MWD, 6-minute walk distance.
Hellenbart EL et al. Pharmacotherapy. 2024;45(2):124-144; Maurer MS et al. N Engl J Med. 2018;379(11):1007-1016; Gillmore JD et al. N Engl J Med. 2024;390(2):132-142; Fontana M et al. N Engl J Med. 2025;392(1):33-44.

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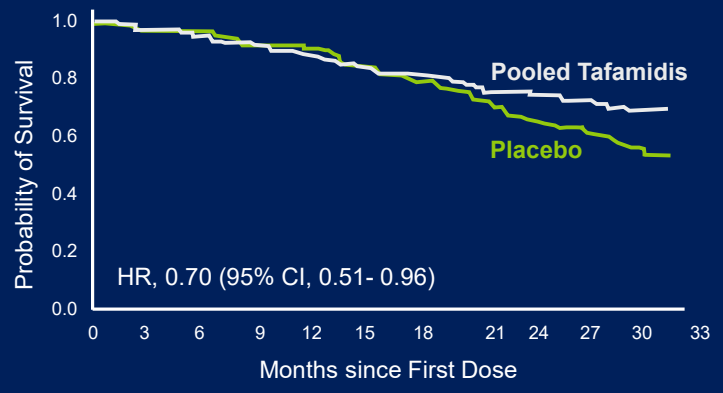
ATTRACT-CM (Tafamidis)

441 patients with ATTR-CM randomized to tafamidis or placebo (~76% wild-type, ~61% NYHA II)



- NNT 8 for death
- Decreased CV hospitalizations RR 0.68 (0.48 vs. 0.70; 95% CI, 0.56 to 0.81; NNT 13)
- Lower rate of decline in 6MWD and KCCQ with tafamidis (p<0.001 for both)
- No difference in adverse events

6MWD, six-minute walk distance; ATTR-CM, transthyretin amyloid cardiomyopathy; CV, cardiovascular; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association
Adapted from: Maurer MS, et al. *N Engl J Med*. 2018 Sep 13;379(11):1007-1016.

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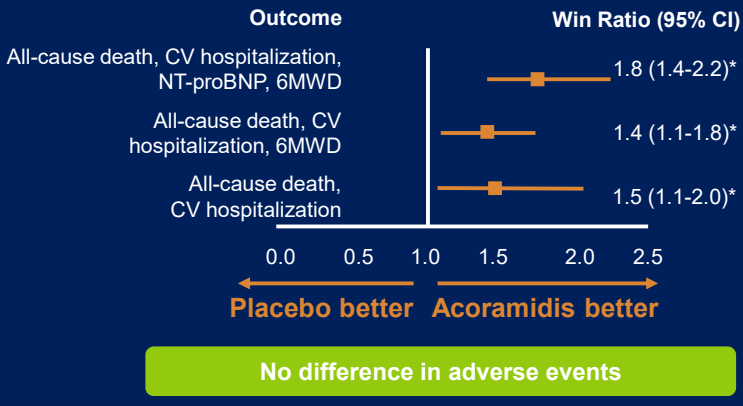
ATTRibute-CM (Acoramidis)

632 patients with ATTR randomized 2:1 to acoramidis or placebo (~90% wild-type, ~72% NYHA II)



No difference in adverse events

- NNT 7 for death or CV hospitalization HR: 0.64; 95% CI 0.50-0.83) (Curves separated at 3 months)
- NNT 5 for annual CV hospitalization RR: 50%; 95% CI: 0.36-0.7
- All-cause mortality 19.3% vs. 25.7% HR 0.77; 95% CI 0.54-1.10

*p<0.001
6MWD, 6 minute walk distance; CV, cardiovascular; CI, confidence interval
Adapted from: Gillmore JD, et al. *N Engl* J Med. 2024 Jan 11;390(2):132-142.
Judge DP, et al. J Am Coll Cardiol. 2025 Mar 18;85(10):1003-1014.

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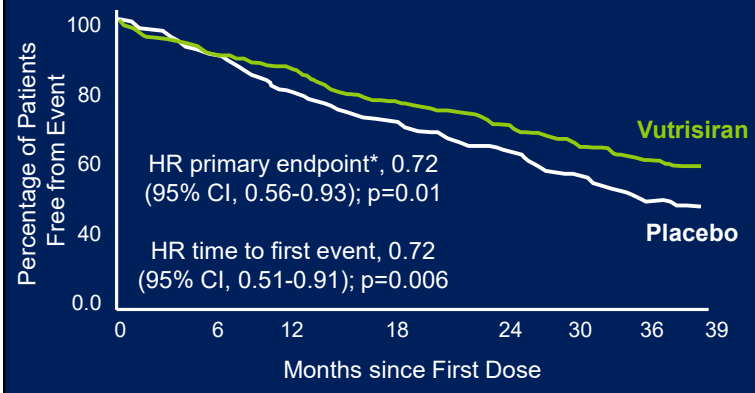
HELIOS-B (Vutrisiran)

655 patients with ATTR-CM randomized 1:1 to vutrisiran or placebo (~88% wild-type, ~78% NYHA II, 40% on tafamidis)



- Less severe disease than ATTRACT
- HR 0.67; p = 0.02 for patients not on baseline tafamidis
- Lower rate of decline in 6MWD with vutrisiran (p<0.001)
- No difference in adverse events

*Composite of all-cause mortality and recurrent CV events
6MWD, six-minute walk distance; ATTR-CM, transthyretin amyloid cardiomyopathy; CV, cardiovascular; NYHA, New York Heart Association
Adapted from: Fontana M, et al. *N Engl J Med* 2024;Aug 30:[Epub ahead of print].

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Long term data

Tafamidis	Acoramidis	Vutrisiran
Real-world multicenter study	ATTRibute-CM extension	HELIOS-B analysis
Over a median of 43 months, 39% of patients died and the probability of survival at 65 months was 54%	Early and continuous treatment results in sustained reduction in mortality through 54 months	Reduced mortality in patients who developed advanced disease by 77%

Masri A et al. JACC CardioOncology 2025 April;7(3):282-293.
Soman P et al. JAMA Cardiology 2026 March 30:e26081.
Witteles R et al. JACC 2026 March; Vol. 87 No.13 Supplement. Moderated Poster Contribution.

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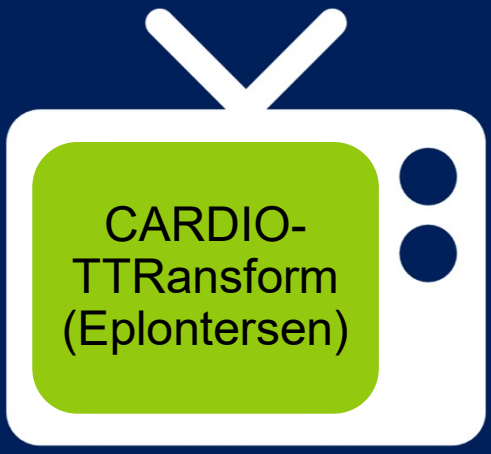
Stay Tuned…



- Phase 3 trial in ATTR-CM (hereditary or wild-type)
- Primary outcome: Composite outcome of CV mortality and recurrent CV clinical events
- Main finding: endpoint did not meet statistical significance
- Full data set due at ESC 8/26

CARDIO-TTRansform. NCT04136171. Updated December 27, 2024. Accessed April 17, 2025. https://www.clinicaltrials.gov/study/NCT04136171; AstraZeneca. News release. July 9, 2026. Accessed August 4, 2026. Update on CARDIO-TTRansform Phase III trial for Wainua (eplontersen) in adults with transthyretin-mediated amyloid cardiomyopathy.

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Additional Pipeline Therapies

Silencers	Stabilizers	Depleters
CRISPR Gene Editing	Acoramidis	Monoclonal antibodies that target and remove amyloid deposits
MAGNITUDE (Phase 3)	ACT-EARLY (phase 3)	CLEOPATTRA (phase 3)
TRITON-CM/PN (Phase 3)		DepleTTR-CM (phase 3)

González-López E et al. Eur Heart J. 2025;46(11):999-1013. Amyloidosis Research Consortium.

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Pharmacotherapy for ATTR

Medication	Acoramidis	Diflunisal	Tafamidis	Eplontersan	Patisiran	Vutrisiran
Mechanism	TTR stabilizers			TTR Silencers		
ATTR-CM FDA Approval	2024	Off-Label	2019	Only approved for ATTR polyneuropathy		March 2025
Landmark Trial in ATTR-CM	ATTRibute-CM 2023		ATTR-ACT 2018	Cardio-TTRansform 2026	APOLLO-B 2022	HELIOS-B 2024
Dose	712 mg orally twice daily	250 mg orally twice daily	61 mg orally once daily	45 mg SC once monthly	0.3 mg/kg (max 30 mg) IV every 3 weeks	25 mg SC every 3 months
Adverse Effects	Well tolerated	Renal dysfunction, bleeding	Well tolerated	Infusion-related/site reactions*, vitamin A deficiency		

*Premedication for patisiran
ATTR, Transthyretin amyloidosis; ATTR-CM, Transthyretin amyloidosis cardiomyopathy; FDA, Food and Drug Administration; GI, gastrointestinal; IV, intravenous; PDUFA, Prescription Drug User Fee Act; SC, subcutaneous; TTR, transthyretin

Kittleson MM, et al. *Circulation*. 2020 Jul 7;142(1):e7-e22.
Gillmore JD, et al. *N Engl J Med*. 2024;390(2):132-142.
Fontana M, et al. *N Engl J Med* 2025;392:33-4.
Maurer MS, et al. *N Engl J Med*. 2018;379(11):1007-1016.
Maurer MS, et al. *N Engl J Med*. 2023;389:1553-1565
Siddiqi OK, et al. *Amyloid*. 2022;29(2):71–78.

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Monitoring Markers of Disease Progression

HF-Related Hospitalization *≥1 event*	NT-proBNP *Increase >700 pg/mL (~30% increase)*	6MWT *Decrease of >35 meters*
Outpatient Diuretic Intensification *Any new loop diuretic or increase in dose within 30 days*	eGFR *Decrease of >20%*	QoL *>5-point decrease in KCCQ or increase in NYHA class*

Disease progression can be considered if at least 2 parameters meet defined thresholds

Garcia-Pavia et al. JACC HF. 2026 Jan;14(1):102766
6MWT = 6-minute walk test
KCCQ = Kansas City Cardiomyopathy Questionnaire
QoL = quality of life

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Panel Discussion

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Patient and Advocate Perspective on Improving coordination and outcomes in ATTR-CM care

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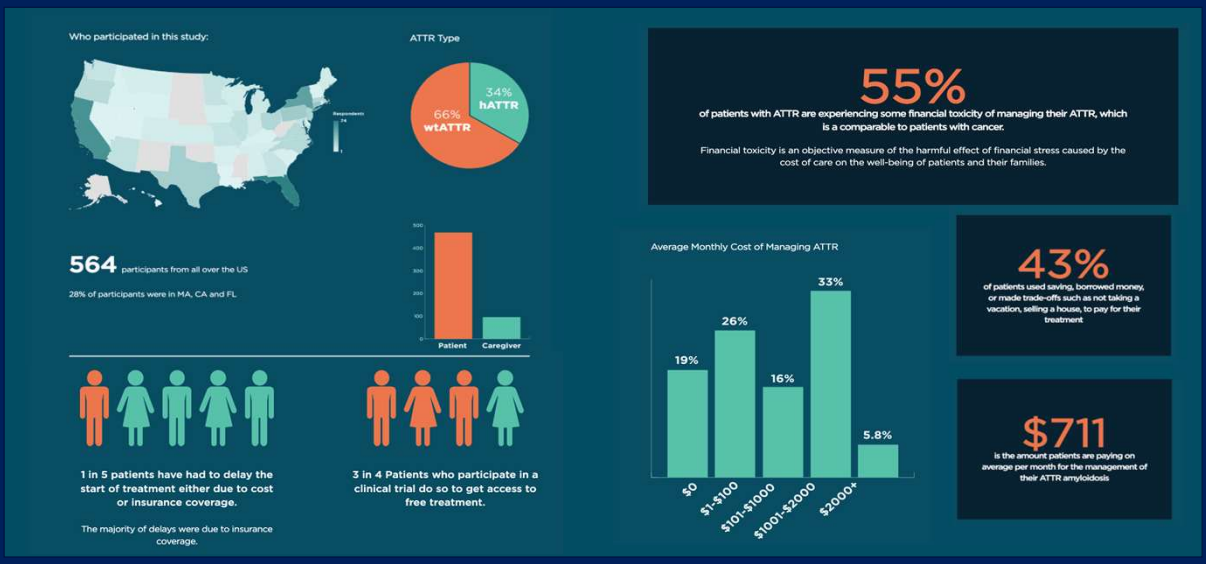
ATTR Affordability Study



Rebello S, et al. Amyloid, 2025;1–10. https://doi.org/10.1080/13506129.2025.2462541

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Considerations

Underdiagnosis	• Increase provider awareness • Implement routine screening • Use genetic testing to enhance early detection.
Limited Access to Effective Therapies	• Expand financial assistance and policy initiatives to reduce cost barriers • Focus on Black American patients that are disproportionately affected • Streamline documentation and prior authorization
Cultural Competency	•Develop community outreach programs •Provide cultural competency training for providers
Underrepresentation in Research	• Promote diverse participation in research studies • Refine recruitment strategies to ensure findings are relevant to all populations
Managed Care and Holistic Support	• Integrate services across specialties • Address physical, emotional, and social needs in managed care plans

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Panel Discussion

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Considerations for Managed Care Management of ATTR-CM

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Regional Impact – Ohio/Kentucky

- ATTR-CM most common in men and the elderly (≥65 years), with ~ 80% of patients covered by Medicare.
- Ohio has the 6th largest Medicare enrollment in the country

State	Total Medicare Enrollment	Estimated Black Population	Estimated V122I Carriers
Ohio	2,535,073	370,374	12,963
Kentucky	988,571	93,321	3,266
Total	3,523,644	463,695	16,229

Sources: Kaiser Family Foundation (KFF). Total Medicare Beneficiaries. KFF State Health Facts. 2024. Available from: https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries; World Population Review. Black Population by State [Internet]. 2024. Available from: https://worldpopulationreview.com/state-rankings/black-population-by-state

The Thr60Ala (T60A, pT80A) variant — known as the "Appalachian mutation" is the second most common hereditary ATTR variant in the United States.

Ruberg, et al. J Am Coll Cardiol. 2019;73(22):2872–2891

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Local Centers of Excellence

Geographic disparities in ATTR-CM prevalence exist across the U.S. and may be driven by healthcare infrastructure and diagnostic capacity.

Ohio

- Cleveland Clinic Amyloidosis Center
- The Ohio State University Comprehensive Amyloidosis Clinic

Kentucky

- None
- Ascension St. Thomas West and Vanderbilt in Nashville, TN

[a]Treatment Centers found through My Amyloidosis Pathfinder (MAP) created by Amyloidosis Research Center.

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ATTR-CM Trends: Managed Care Impact

- **Earlier diagnosis with improved diagnostics**
  - U.S. ATTR-CM population likely >200,000
  - ~15,000 new patients starting therapy annually
- **Combination therapy**
  - Monotherapy = $3 PMPM (1MM Medicare plan)
  - ICER: vutrisiran + tafamidis show added benefit
  - Not currently supported for routine coverage
- **Medicare Part D redesign**
  - Shifting cost burden may increase plan liability
  - Reduced out-of-pocket costs & smoothing payments for patients

Open Heart. 2025;12(2):e003781
Alnylam Pharmaceuticals. Investor presentation. March 2026.
Wasfy JH, et al. ICER. 2024, September 5.

Most ATTR-CM patients are covered by Medicare, but utilization of therapy varies widely across plans.

Plan Size	Utilizers	Utilization Rate per 1,000
45,000 members	30	0.67
14,500 members	4	0.28
7,000 members	16	2.29
4,600 members	3	0.65
3,500 members	6	1.71

Source: IPD Analytics

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Current Coverage Trends

- IPD Analytics tracks formulary coverage across >300 Medicare plans (Advantage and PDP) and ~140 Commercial and ACA plans.
- Of the "Big 3" PBMs, only Optum excludes an ATTR-CM product: Attruby (Vyndamax preferred)

Drug	Medicare Coverage			Commercial and ACA Coverage			
	Not Listed	Specialty	Covered + Brand	Not Listed + Non-Form	Specialty	NP Specialty	Brand + NP Brand
Vyndamax (tafamidis)	60%	31%	9%	31%	56%	11%	1%
Attruby (acoramidis)	58%	32%	10%	44%	42%	8%	6%
Amvuttra* (vutrisiran)	100%	N/A	N/A	93%	3%	2%	2%

Source: IPD Analytics, Access Hub. All numbers rounded to nearest 1%. *Please note Amvuttra is a typically a medical benefit drug and may not be represented on most payer formularies.

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Managed Care Strategies

- **Preferred products**
  - Clinical trials make direct comparisons difficult
  - Review net costs
  - Preferred TTR stabilizer before Amvuttra (medical)
- **Value-based agreements**
  - Ensure reimbursement is congruent with the health benefit provided
  - Outcomes = CVH and UHF visits identified through medical claims data
- **Vyndamax generics**
  - Likely in mid-to-late 2031
  - ~3 possible manufacturers; annual cost likely still >$100K
- **Restrict combination therapy**

Prior authorization recommended for all agents:
- **Confirmed ATTR-CM Diagnosis**
- **Documentation demonstrating evidence of diagnosis (genetic testing, biopsy, ECG, etc.)**
- **Clinical signs/symptoms consistent with heart failure (NYHA Class I-III, not Class IV)**

Drug	Vyndamax (tafamidis)	Attruby (acoramidis)	Amvuttra (vutrisiran)
MOA	TTR Stabilizer	TTR Stabilizer	TTR Silencer
ATTR-CM Approval	2019	2024	2025
Dosing	Oral, daily	Oral, twice daily	HCP-administered SC, every 3 months
Annual WAC	$286,654	$257,977	$477,404

Abbreviations: Mechanism of action, MOA; Healthcare professional, HCP; Subcutaneous, SC; Wholesale acquisition cost, WAC.
Source: IPD Analytics, April 20, 2026.

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Panel Discussion

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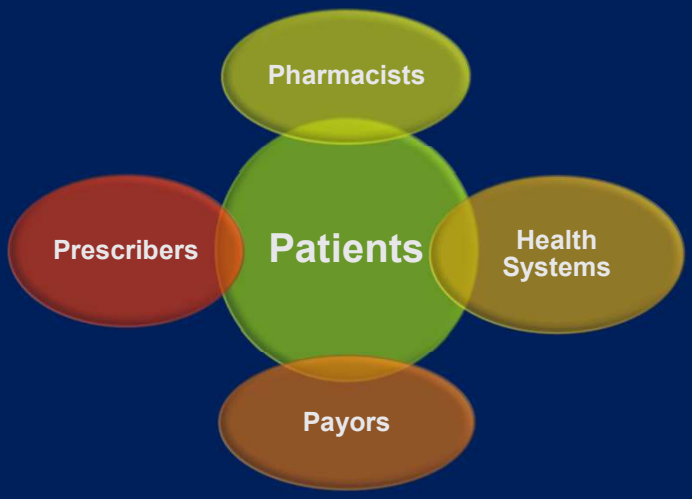
How do we work together?



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FACULTY BIOGRAPHY

Catherine Berger, PharmD **Clinical Advisor** **Employers Health**	As a clinical advisor, Catherine works with the Employers Health clinical team to provide clinical insight, enhance plan design recommendations and summarize overall marketplace trends for more than 475 self-insured plan sponsors. With a strong passion for teaching and training, Catherine serves as the Employers Health residency program coordinator and leads outreach efforts to pharmacy students interested in pursuing careers in managed care. Catherine earned her Doctor of Pharmacy from The Ohio State University and her Master of Business Administration with a concentration in organizational leadership from Youngstown State University.
Andres Carmona Rubio, MD **Cardiologist** **Heart Failure & Cardiac Transplantation & Amyloidosis Center** **Cleveland Clinic**	Andres Carmona Rubio, MD, is a cardiologist at Cleveland Clinic specializing in advanced heart failure, cardiac transplantation, and amyloidosis. He completed medical school in Venezuela, internal medicine residency at the University at Buffalo, cardiology training at Cleveland Clinic Florida, and advanced heart failure and transplant training at Cleveland Clinic. He currently serves as a staff physician in the Advanced Heart Failure and Transplant section and as a member of Cleveland Clinic's Amyloidosis Center. Dr. Carmona Rubio also serves as the liaison to the Internal Medicine Residency for heart failure at Cleveland Clinic and is a member of the Audit Committee at the Heart Failure Society of America.
Alyssa Guest, PharmD **Associate Director, Clinical Pharmacy** **IPD Analytics**	Alyssa Guest is currently an Associate Director of Clinical Pharmacy at IPD Analytics, providing formulary, clinical, contracting, and market-access decision-making support with curated insights and analysis. Alyssa received her Doctor of Pharmacy degree from Midwestern University in Illinois. Following graduation, she trained as a PGY-1 Managed Care pharmacy resident with Blue Cross Blue Shield of Michigan and the University of Michigan.
Erin Poyant **Senior Manager of Education and Awareness** **Amyloidosis Research Consortium**	Erin Poyant has nearly 25 years of experience in research, spanning roles in clinical trial coordination, regulatory management, and clinical laboratory oversight across various hospitals and research groups. As the Senior Manager of Education and Awareness at the Amyloidosis Research Consortium (ARC); Erin leads educational initiatives and awareness campaigns for various forms of amyloidosis. Her personal connection to the disease, through her late father who passed away in 2020 due to the V122i variation of hereditary amyloidosis, fuels her commitment to improving patient outcomes through strategic partnerships and community outreach. Recently, she founded #hattrnextgen™ to spread awareness about hereditary amyloidosis to the younger Black community through the use of social platforms. Erin's work at ARC reflects her commitment to the fight against amyloidosis, by contributing to a team highly dedicated to advancing research, education, and patient care.

Tara E. Shreck, PharmD, BCACP Clinical Pharmacist, OhioHealth Riverside Methodist Hospital	Tara E. Schreck, PharmD, BCACP received her Doctor of Pharmacy degree from Ohio Northern University. She completed a Community Care Residency at Kids n Cures Pharmacy in Boardman, Ohio. For over twenty years, she has worked at OhioHealth in Columbus, Ohio. Tara provided clinical services as part of the following inpatient pharmacy teams for over five years: medicine, surgery, NICU, oncology, investigational drugs, and women's health. For nearly nine years, she established and served as lead pharmacist for the OhioHealthy Pathways to Wellness Program, a diabetes and asthma management program for associates and dependents. Tara helped to establish the OhioHealth Ambulatory Care PGY2 Residency and served as the Residency Program Director for four years. For the past ten years, Tara has been a clinical pharmacist in the OhioHealth Advanced Heart and Vascular Center helping optimize medication for patients with heart failure. Her professional passions include cardiac amyloidosis, safe medication in lactation and hypertensive disorders of pregnancy. Spending time with her husband and four children remain the proudest and fondest moments in life.

FINANCIAL RELATIONSHIP DISCLOSURES

Faculty/Reviewer/Planner	**Reported Relevant Financial Relationships**
Catherine Berger, PharmD *Moderator*	Disclosed no relevant financial relationships.
Andres Carmona Rubio, MD *Faculty*	Alnylam: Advisory Board; BridgeBio: Advisory Board, Peer Reviewer; Pfizer: Advisory Board
Alyssa Guest, PharmD *Faculty*	Disclosed no relevant financial relationships.
Erin Poyant *Faculty*	Disclosed no relevant financial relationships.
Tara E. Shreck, PharmD, BCACP *Moderator*	Disclosed no relevant financial relationships.
Drake Reiter, PharmD *Peer Reviewer*	Disclosed no relevant financial relationships.
Angela Cassano, PharmD, BCPS, FASHP *Planner*	Disclosed no relevant financial relationships.
Brittany V. Henry, PharmD, MBA *Planner*	Disclosed no relevant financial relationships.

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