

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

Stormi Gale, PharmD, BCCP, BCPS, FHFA, FACC

Cardiology Pharmacy Specialist, Atrium Health Carolinas Medical Center

Alyssa Guest, PharmD

Associate Director, Clinical Pharmacy, IPD Analytics

Erin Poyant

Senior Manager of Education and Awareness, Amyloidosis Research Consortium

Jai Singh, MD

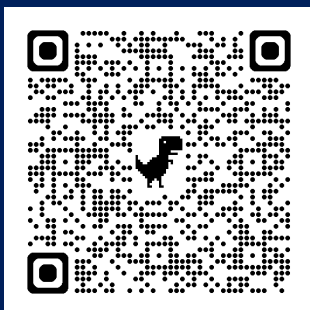
Director, Cardio-Oncology and Cardiac Amyloidosis, Atrium Health Sanger Heart and Vascular Institute



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

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



**Stormi Gale, PharmD,
BCCP, BCPS, FHFSA,
FACC**

Cardiology Pharmacy
Specialist, Atrium Health
Carolinas Medical Center



**Alyssa Guest,
PharmD**

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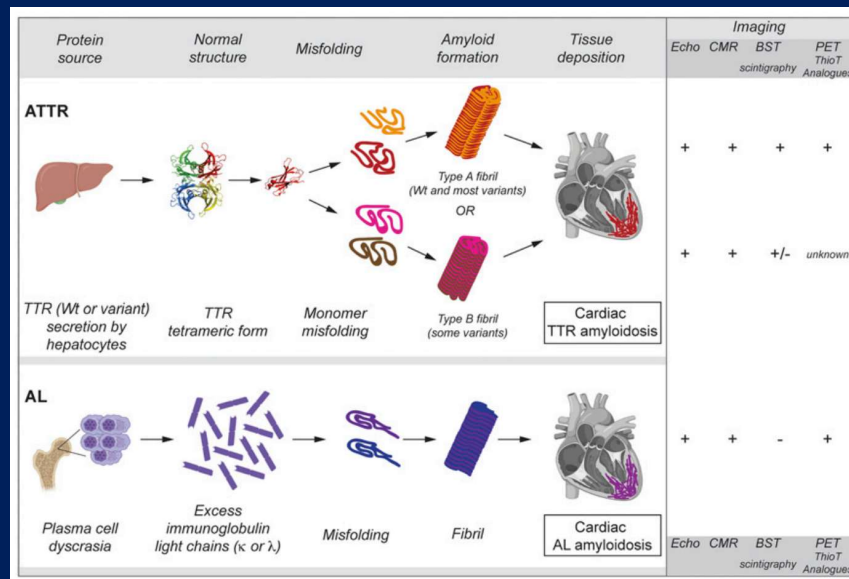


Jai Singh, MD

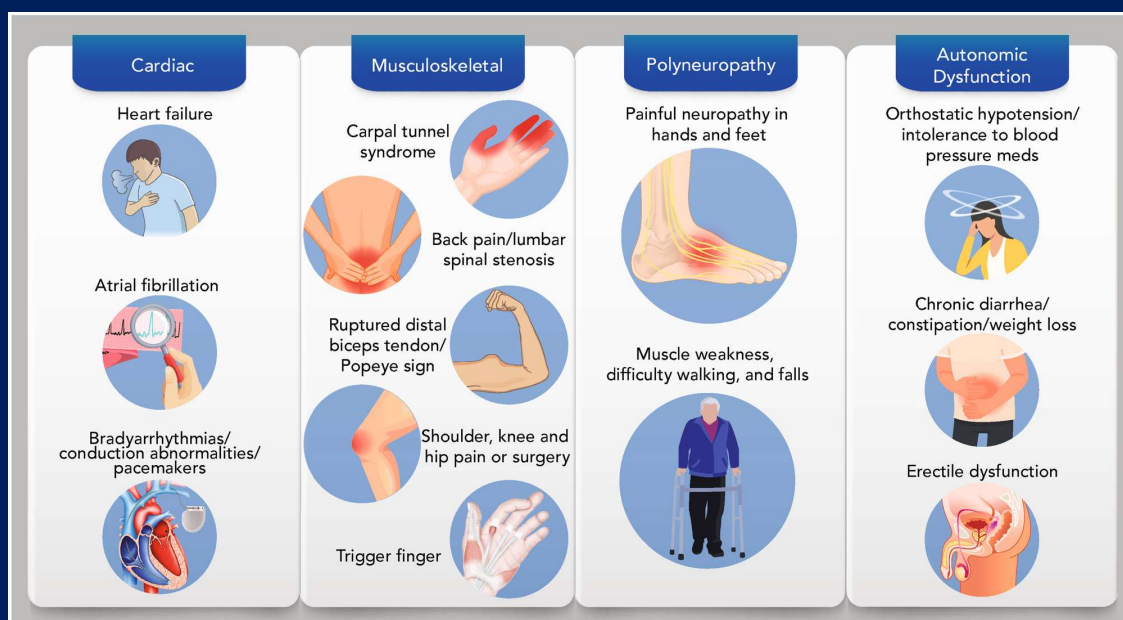
Director, Cardio-Oncology and
Cardiac Amyloidosis, Atrium
Health Sanger Heart and
Vascular Institute

Transthyretin Amyloidosis

Cardiac Amyloidosis



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



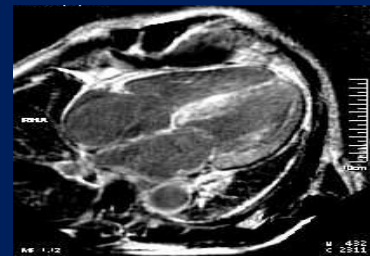
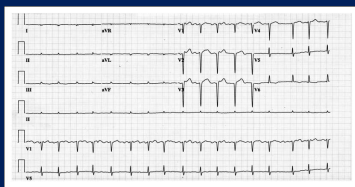
Nativi-Nicolau, J.N., Karam, C., Khella, S. et al. *Heart Fail Rev* 27, 785–793 (2022). <https://doi.org/10.1007/s10741-021-10080-2>.
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Think Amyloidosis – Practical Recommendations

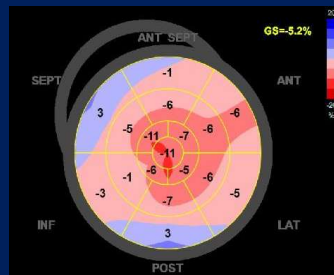
- Carpal tunnel syndrome in patients > 60 years of age
 - Atraumatic, not related to rheumatological condition or ongoing occupational exposure
 - Especially when bilateral
- Coexistent unexplained neuropathy
- Heart failure with any of the following:
 - Autonomic dysfunction features
 - Any unexplained 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>.

Traditional Approach



Low voltage 50% in AL
Low voltage 25% in ATTR

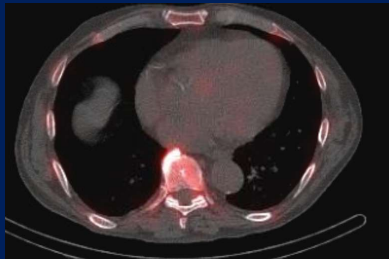
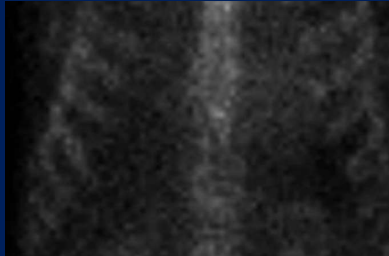


Images courtesy of Ahmad Masri

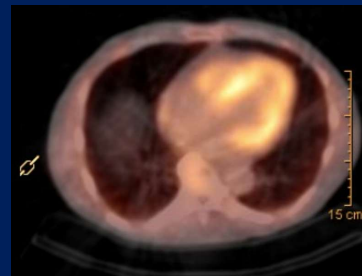
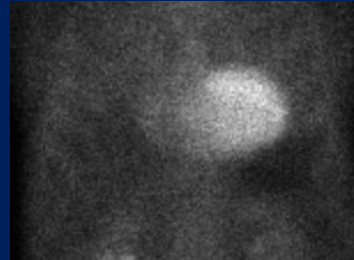
Technetium pyrophosphate scintigraphy (Tc-PYP) DPD/H(M)DP



Negative scan

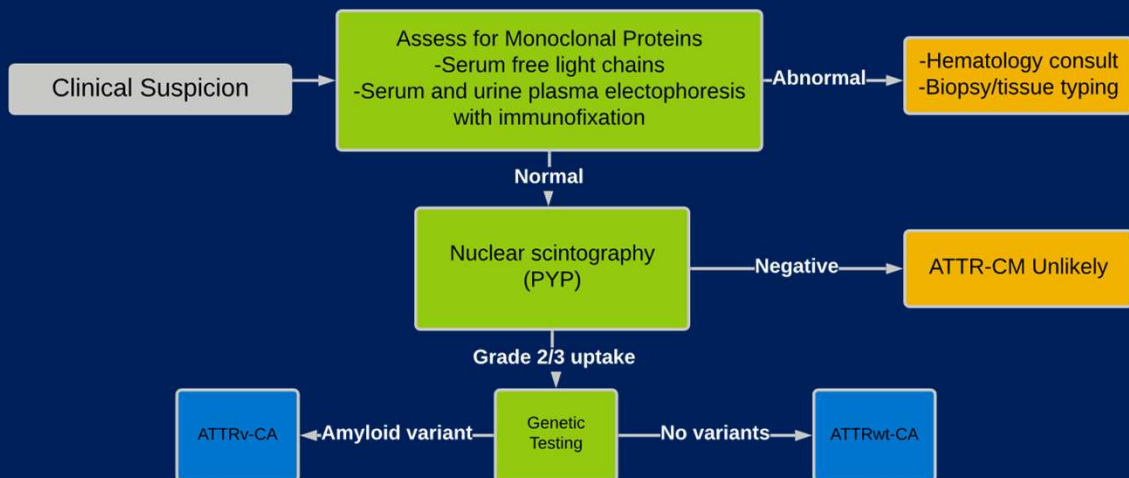


Positive scan



Images courtesy of Ahmad Masri

Diagnosis of Suspected ATTR-CM



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

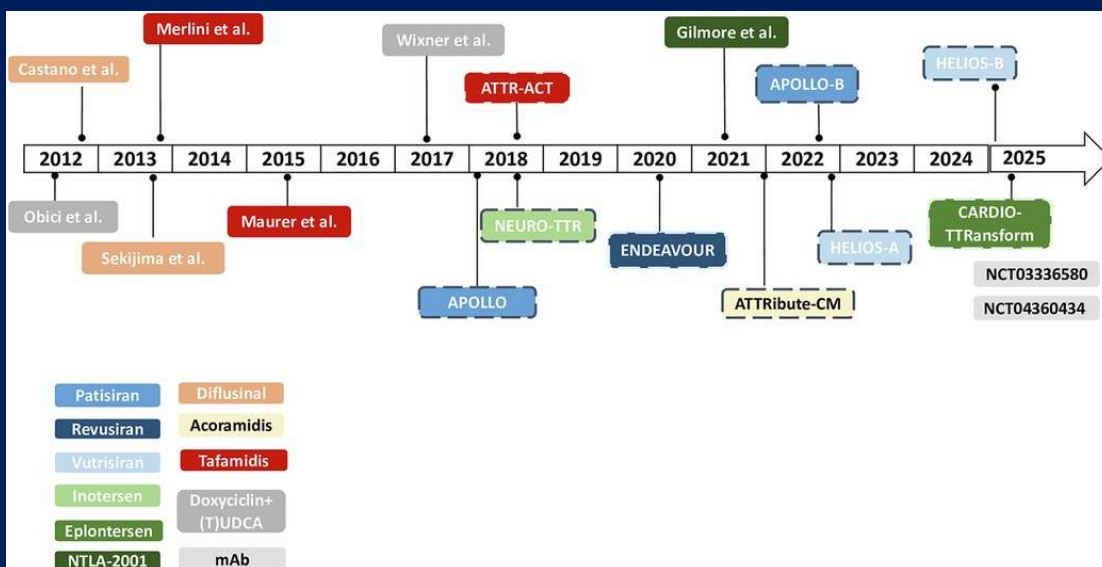
Diagnostic Pathways

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

New and Novel Treatment Advances for ATTR-CM



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/>

Disease-Targeted Therapies

Silencers



Inhibit hepatic synthesis of TTR

Eplontersen

Patisiran

Vutrisiran*

Stabilizers



Prevent TTR misfolding

Acoramidis*

Diflunisal

Tafamidis*

Disrupters

Increases clearance of amyloid fibrils from tissues

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.

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

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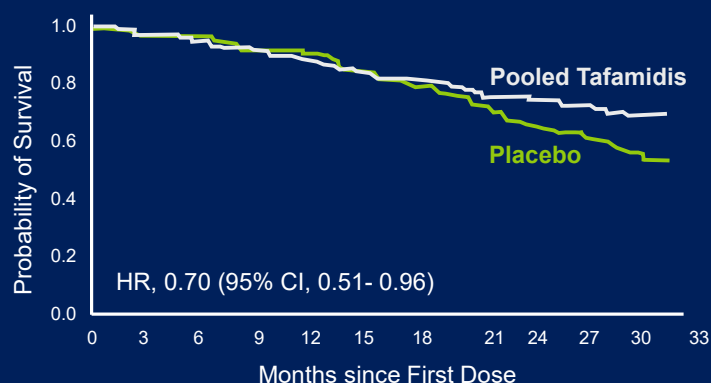
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Baseline Characteristic	ATTR-ACT (Tafamidis)	ATTRibute-CM (Acoramidis)	HELIOS-B (Vutrisiran)
Age, years (median)	74	77	77
NYHA class, %			
I	8	11	13
II	60	72	78
III	32	17	9
6MWD, m (mean)	353	348	375
NT-proBNP, pg/mL (median)	3161	2306	1813
ATTRv (%)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

*Limited to trials of agents FDA approved for use in ATTR-CM
 NT-proBNP, N-terminal pro-B-type natriuretic peptide; AF, atrial fibrillation; NYHA, New York Heart Association; 6MWD, 6-minute walk distance.
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 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.

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)

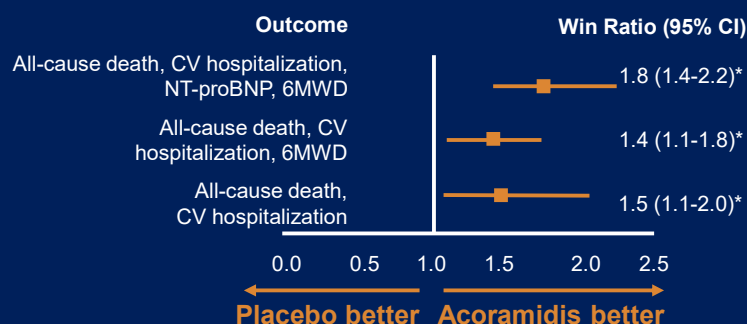
Lower rate of decline in 6MWD and KCCQ with tafamidis (p<0.001 for both)

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.

ATTRibute-CM (Acoramidis)

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



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

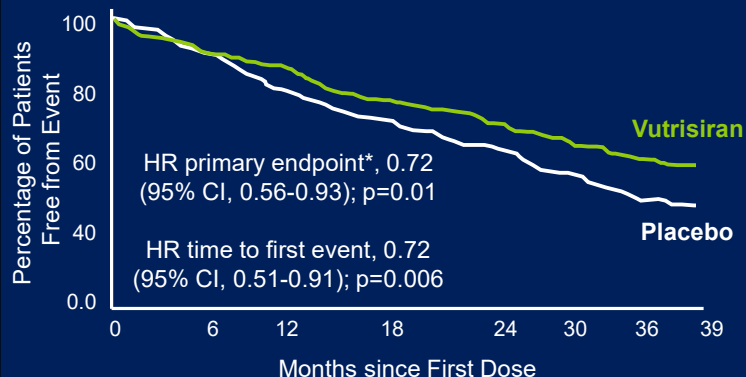
All-cause mortality 19.3% vs. 25.7%
HR 0.77; 95% CI 0.54-1.10

No difference in adverse events

*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.

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].

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%

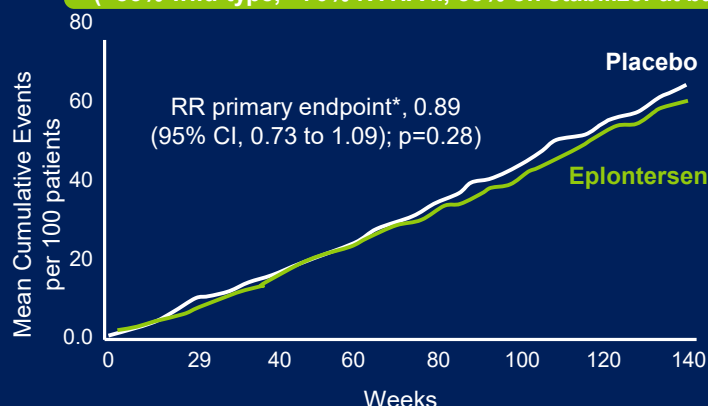
Early and continuous treatment results in sustained reduction in mortality through 54 months

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.

CARDIO-TTRansform (Eplontersen)

1432 patients with ATTR-CM randomized 1:1 to eplontersen or placebo
(~85% wild-type, ~70% NYHA II, 58% on stabilizer at baseline; 24% started stabilizer during trial)



RR 0.71 (95%CI, 0.54-0.93) for patients not on baseline stabilizer

RR 0.63 (95%CI, 0.47-0.84) in NAC stage 1 subgroup

Lower rate of decline in 6MWD and KCCQ with eplontersen

No difference in adverse events

*Composite CV death and recurrent CV clinical events
6MWD, six-minute walk distance; ATTR-CM, transthyretin amyloid cardiomyopathy; CV, cardiovascular; KCCQ, Kansas City Cardiomyopathy Questionnaire; NAC, National Amyloidosis Centre; NYHA, New York Heart Association
Adapted from: Fontana M, et al. N Engl J Med. 2026 Aug 28.;[Epub ahead of print].

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NYHA Class	I-III symptoms	I-III symptoms	I-III symptoms Excluded NYHA III at high risk	I-III symptoms
6MWD	≥100 m	≥150 m	≥150 m	≥100 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)	≥600 pg/mL
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	Composite CV death and recurrent CV clinical events at 140 weeks

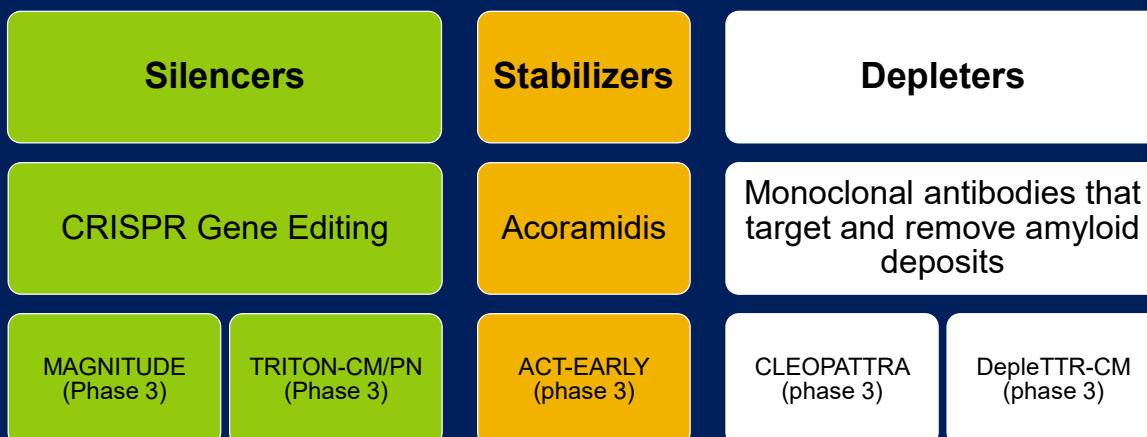
NT-proBNP, N-terminal pro-B-type natriuretic peptide; AF, atrial fibrillation; NYHA, New York Heart Association; 6MWD, 6-minute walk distance.
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III	32	17	9	17
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Fontana M et al. N Engl J Med. 2025;392(1):33-44. Fontana M, et al. N Engl J Med. 2026 Aug 28. [Epub ahead of print].

Additional Pipeline Therapies



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

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-TTRransform 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.

Monitoring Markers of Disease Progression

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

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

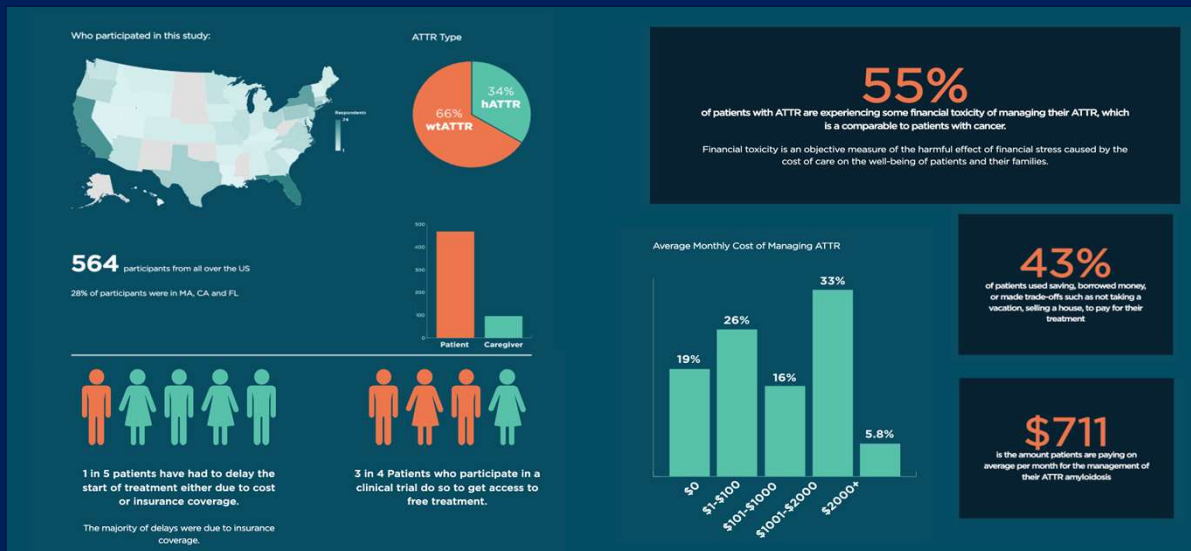
Garcia-Pavia et al. *JACC HF*. 2026 Jan;14(1):102766
 6MWT = 6-minute walk test
 KCCQ = Kansas City Cardiomyopathy Questionnaire
 QoL = quality of life

Panel Discussion



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

ATTR Affordability Study



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

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

Panel Discussion



Considerations for Managed Care Management of ATTR-CM

Regional Impact – Carolinas



- ATTR-CM most common in men and the elderly (≥ 65 years), with $\sim 80\%$ 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
North Carolina	2,228,458	481,124	16,839
South Carolina	1,230,384	310,549	10,869
Total	3,458,842	791,673	27,708

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>

Both North and South Carolina are popular retirement destination states → larger potential population of ATTRwt patients

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.

North Carolina

- Duke Precision Cardiomyopathy Amyloidosis Center
- University of North Carolina at Chapel Hill

South Carolina

- Medical University of South Carolina
- Prisma Health Greenville
- Prisma Health Richland

^aTreatment Centers found through My Amyloidosis Pathfinder (MAP) created by Amyloidosis Research Center.

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

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

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

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.

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.

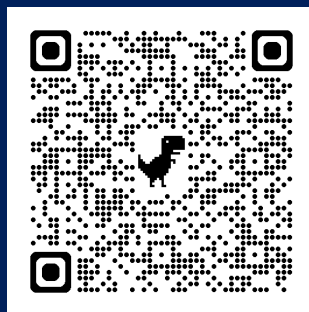
Panel Discussion

How do we work together?



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Sources of all images are provided in citations.

FACULTY BIOGRAPHY

Molly Borchardt, PharmD Vice President, Director PrecisionAQ	Molly Borchardt, PharmD, is a Vice President, Director of Precision AQ's Access Experience Team. Molly brings over 12 years of specialty and managed care experience, particularly in specialty drugs, medical and pharmacy benefit management, medical drug management and reimbursement, utilization management, specialty pharmacy networks, and rare diseases. Prior to joining Precision AQ in 2023, Molly was the Director, Specialty Pharmacy and Innovation, at Blue Cross and Blue Shield of North Carolina (Blue Cross NC), where she led strategy and execution of specialty drug management and implementation of other innovative solutions. Her work focused on specialty network strategy and coordination of medical and pharmacy specialty drug clinical programs, with a particular interest in rare disease and high-cost therapy management. Previously Molly held various roles at Prime Therapeutics collaborating with Prime's clinical and client engagement internal teams to design and implement client-specific solutions in the area of specialty pharmacy.
Stormi Gale, PharmD, BCCP, BCPS, FHFSA, FACC Cardiology Pharmacy Specialist, Atrium Health Carolinas Medical Center	Dr. Gale is a cardiology clinical pharmacy specialist and cardiology clinical coordinator at Atrium Health Carolinas Medical Center in Charlotte, NC. She earned her Doctor of Pharmacy from Wingate University. She completed her PGY1 at Novant Health Presbyterian Medical Center and her PGY2 cardiology specialty residency at the University of Maryland School of Pharmacy. Dr. Gale is a Fellow of the Heart Failure Society of America and American College of Cardiology.
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 #hattnextgen™ 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.

Jai Singh, MD Director, Cardio-Oncology and Cardiac Amyloidosis, Atrium Health Sanger Heart and Vascular Institute	Dr. Jai Singh is Director of Cardio-Oncology and Cardiac Amyloidosis at Atrium Health Sanger Heart and Vascular Institute. He specializes in cardiac amyloidosis, advanced cardiac imaging, and population health, with a focus on using decentralized advanced imaging, AI, and innovative care models to improve detection of cardiac amyloidosis and bring speciality expertise into routine clinical practice.
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FINANCIAL RELATIONSHIP DISCLOSURES

Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Molly Borchardt, PharmD <i>Moderator</i>	Disclosed no relevant financial relationships.
Stormi Gale, PharmD, BCCP, BCPS, FHFSa, FACC <i>Faculty</i>	Faculty/Speaker: American Regent
Alyssa Guest, PharmD <i>Faculty</i>	Disclosed no relevant financial relationships.
Erin Poyant <i>Faculty</i>	Disclosed no relevant financial relationships.
Jai Singh, MD <i>Faculty</i>	Consulting: AstraZeneca
Drake Reiter, PharmD <i>Peer Reviewer</i>	Disclosed no relevant financial relationships.
Angela Cassano, PharmD, BCPS, FASHP <i>Planner</i>	Disclosed no relevant financial relationships.
Brittany V. Henry, PharmD, MBA <i>Planner</i>	Disclosed no relevant financial relationships.

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