VANDERBILT HEALTH | Specialty Pharmacy

# Accelerating Access to Acoramidis for Patients with ATTR-CM: An Effective Pre-Launch Manufacturer-HSSP Collaboration

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## Background

Acoramidis, a limited distribution drug, was FDA approved in November 2024 for the treatment of transthyretin cardiac amyloidosis (ATTR-CM). Before market launch, its manufacturer collaborated with an integrated health-system specialty pharmacy (HSSP) to identify and prevent potential medication access barriers and optimize assistance programs.

## Purpose

1. Describe a manufacturer and HSSP collaborative medication launch strategy prior to and following approval of acoramidis for the treatment of ATTR-CM
2. Quantify early metrics related to medication access and the patient journey

## Methods

### STUDY DESIGN AND SETTING

Single-center, retrospective chart review

Vanderbilt Health outpatient cardiology clinics

### STUDY POPULATION

Inclusion Criteria: Patients with a prescription of acoramidis from January 2025 – May 2025

Exclusion Criteria: Patients < 18 years old; Diagnosis of AL amyloidosis (primary amyloidosis) or multiple myeloma; Patient received chemotherapy or heart, liver, or kidney transplant from 2016-2022.

## Collaboration Process and Outcomes

### Pre-Launch Collaboration Goals (November 2024)

- Identify and prevent potential medication access barriers
- Streamline HUB services and optimize patient assistance programs

### Launch Implementation (January 2025)

Implement standardized data collection form in the electronic health record

### Post-Launch Outcomes (January-May 2025)

- Number of new acoramidis prescriptions
- Time and pathway to payer approval
- Cancellation rate
- HSSP fulfillment rate
- HSSP turnaround time (TAT): number of days from prescription generation to medication shipment
- Proportion of Days Covered (PDC) at 4 and 12 months
- Retention rate

## CONCLUSION

- A manufacturer-HSSP pre-launch collaboration led to **high uptake and fulfillment** with **fast turnaround times** in the initial months of acoramidis launch.
- **High adherence rates** (97-100%) were seen during the first year of acoramidis treatment for patients filling at a HSSP.

## Results

### Table 1. Baseline Demographics

| Characteristic | N (%) N=20 |
|---|---|
| **Sex**, male | 19 (95) |
| **Race**, white | 15 (75) |
| **Age**, years [median (IQR)] | 75 (70-82) |
| **Pharmacy Insurance** | |
| Commercial | 5 (25) |
| Medicare | 15 (75) |
| **Treatment Naïve**, yes | 6 (30) |
| **Variant Genotype**, yes | 5 (25) |

IQR: interquartile range

### Table 2. Outcome Rates

| Rate | N (%) |
|---|---|
| **Abandonment,** yes | 0 (0) |
| **Cancellation**, yes | 1 (5) |
| **HSSP Fulfillment**, yes | 18 (95) |
| **HSSP Retention**, yes | 18 (100) |

**4-month PDC**

**1.00** (IQR 0.97-1.00)

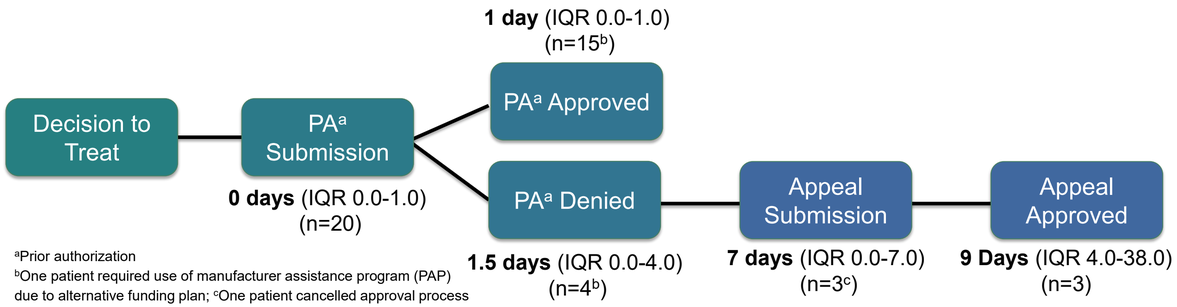


**12-month PDC**

**0.99** (IQR 0.97-1.00)



### Figure 2. Median Time to Medication Approval




[a]Prior authorization
[b]One patient required use of manufacturer assistance program (PAP) due to alternative funding plan; [c]One patient cancelled approval process

### HSSP TAT

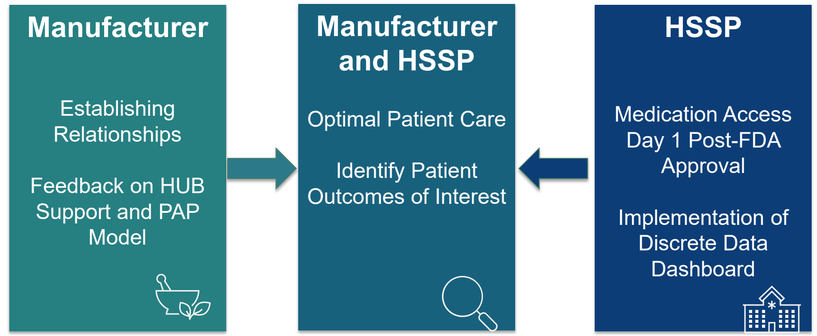
Overall Median Turnaround Time (TAT):
**2 days** (IQR 1-8)
(n=18)

TAT if Appeal Required:
**3 days** (IQR 0-21)
(n=3)

TAT if No Appeal Required:
**2 days** (IQR 1-8)
(n=15)

### Table 3. Financial Assistance

| Assistance Type | N (%)* n=19 |
|---|---|
| **External Grant,** yes | 7 (37) |
| **Free trial program,** yes | 4 (21) |
| **None,** yes | 4 (21) |
| **Internal Grant,** yes | 3 (16) |
| **Manufacturer Copay Card,** yes | 2 (11) |
| **Manufacturer PAP,** yes | 1 (5) |

* Patients may use more than 1 assistance type

### Figure 3. Manufacturer-HSSP Collaboration Benefits