
Lowell
Therapeutics™

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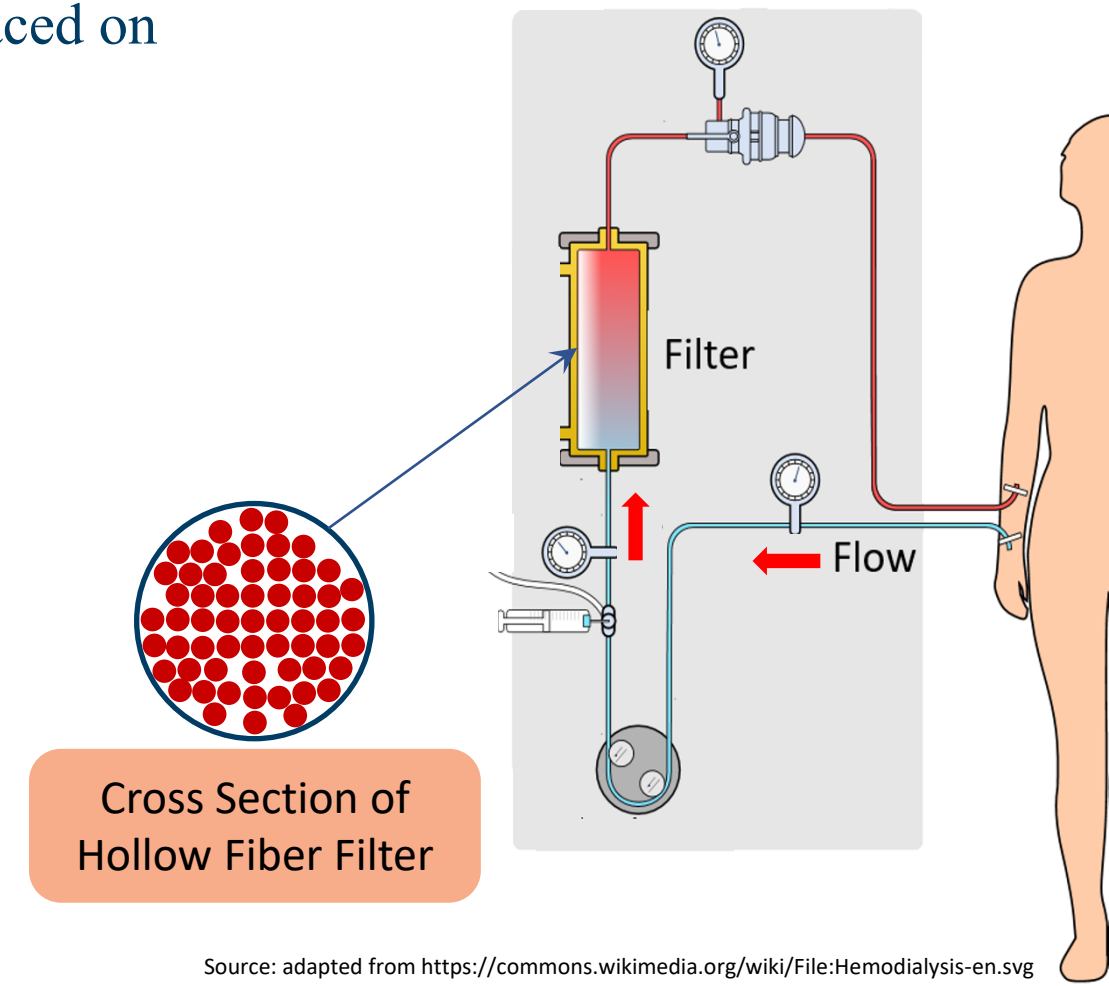
Niyad Satisfies Unmet Need in CRRT

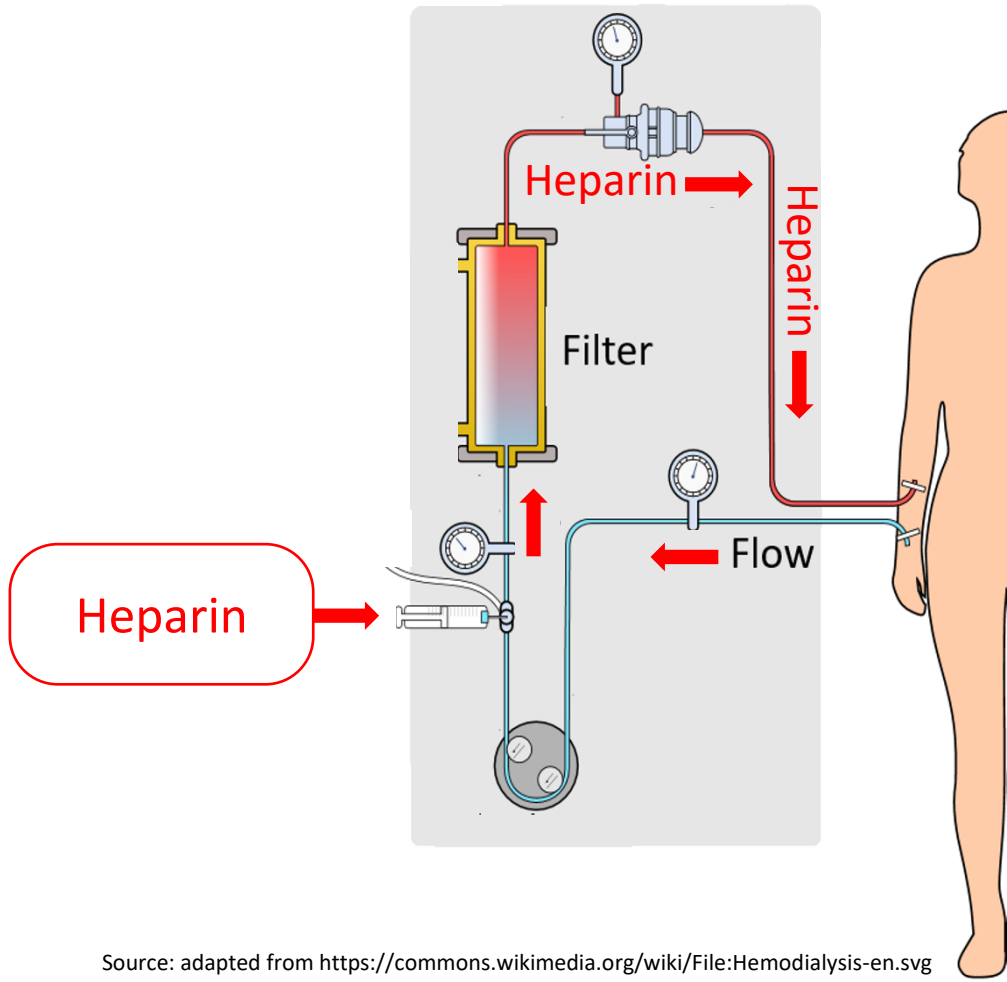
- Patients with sudden kidney failure in the ICU are placed on an artificial kidney machine, which is dialysis 24/7 (continuous renal replacement therapy, CRRT)
- Blood Clots – Cause
  - Exposure of blood to the dialysis filter causes clotting
- Blood Clots – Effect
  - More frequent filter changes
  - Increased blood loss, increased platelet transfusions
  - Delayed/prolonged treatment time
  - Places a burden on doctors and nurses
- Primary filter anticoagulants used: Heparin & Citrate
- Niyad is an anticoagulant without the significant concerns & challenges associated with Heparin or Citrate



Source: adapted from https://commons.wikimedia.org/wiki/File:Hemodialysis-en.svg

Standard of Care Option 1 – Heparin

- Heparin is a systemic anticoagulant
- Clinicians fear over anticoagulating the patient
- **Contraindicated in patients at risk of bleeding**
- Patients can develop heparin resistance, which requires discontinuation of administration, and thus no anticoagulation
- Can cause heparin induced thrombocytopenia (HIT), a potentially fatal immunologic complication
- Used in about 35% of CRRT patients [1]

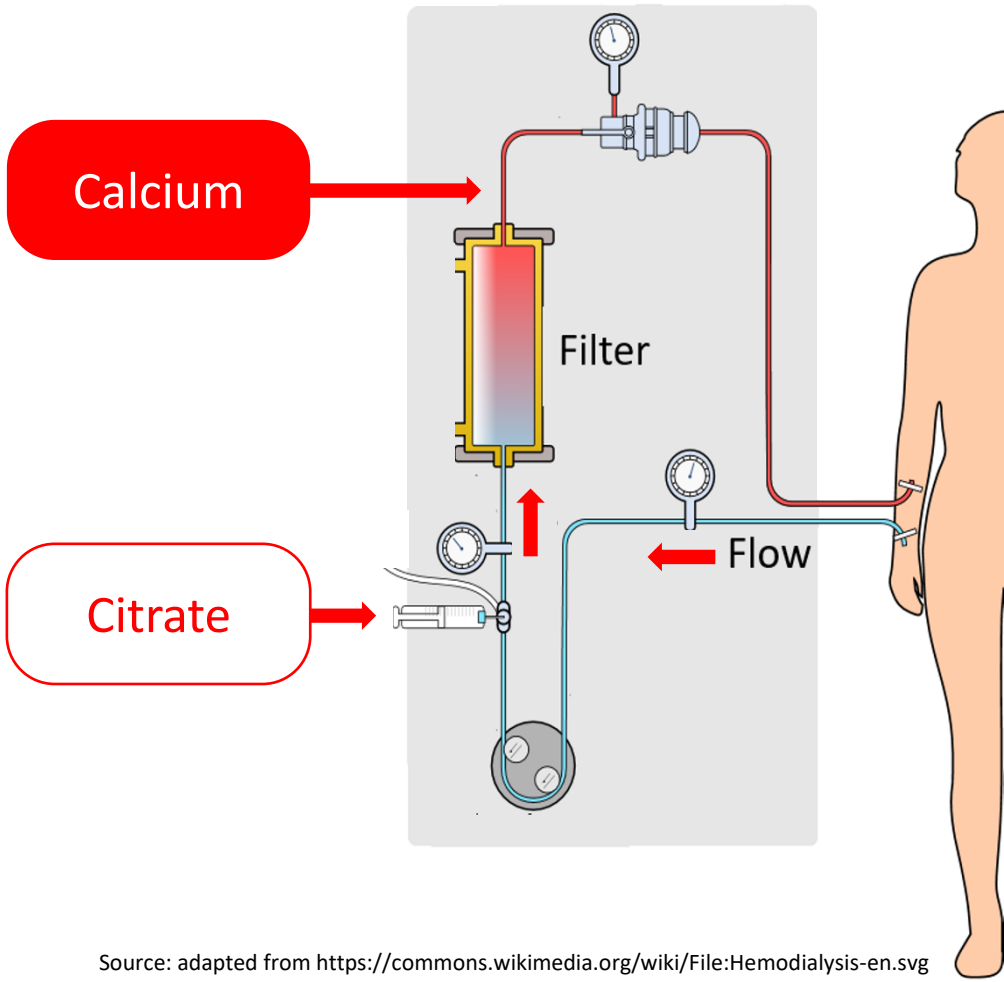


Source: adapted from https://commons.wikimedia.org/wiki/File:Hemodialysis-en.svg

1. Company estimate.

Standard of Care Option 2 – Citrate

- **Requires infusion of calcium (reversal agent & Achilles' heel)**
  - Frequent blood sampling for monitoring
  - Requires advanced training
  - May experience pump asynchrony
  - Labor intensive
  - Calcium is frequently on FDA's drug shortage list
- Contraindicated in patients with liver failure (43% of AKI patients[1])
- Sometimes made by compounding pharmacies
- FDA EUA status only
- Used at 40% of hospitals in the US, but overall in only ~5% of patients[2]



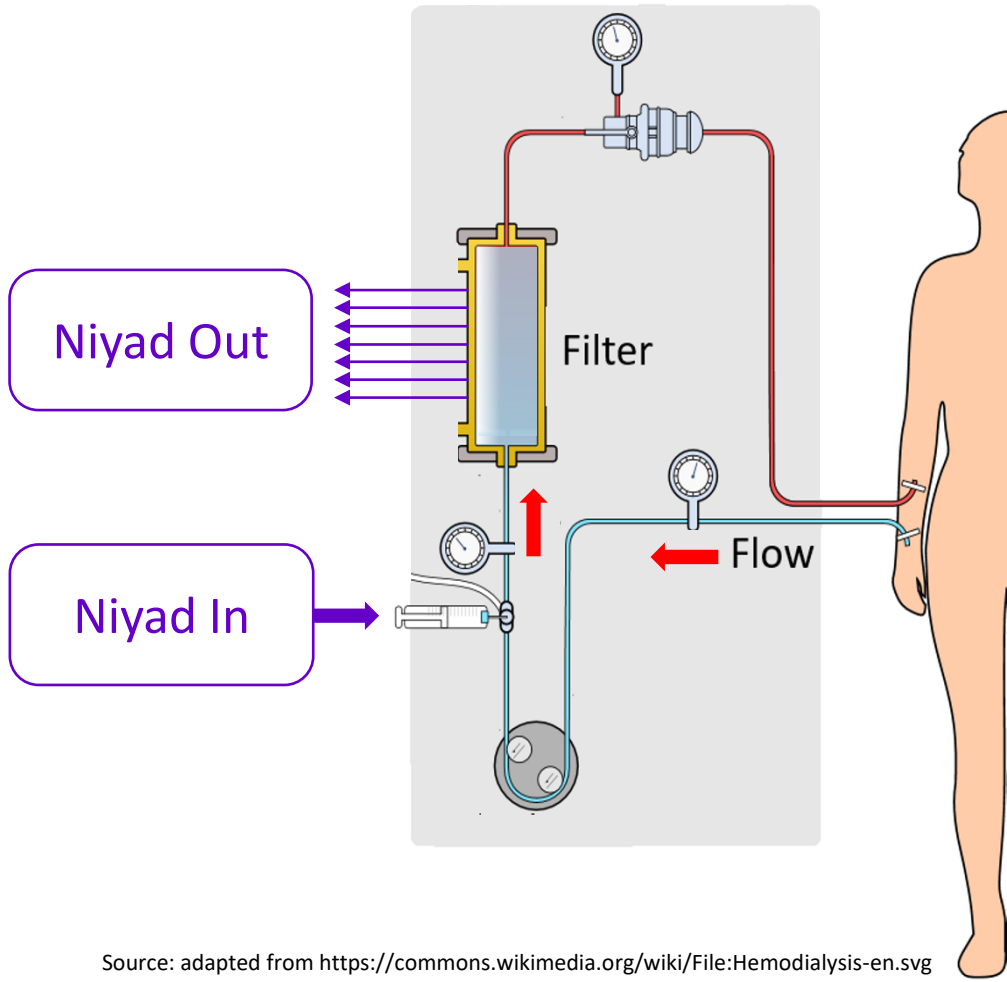
Source: adapted from https://commons.wikimedia.org/wiki/File:Hemodialysis-en.svg

1. Mehta. Kidney International, Vol. 60 (2001), pp. 1154–1163.
2. Company estimate.

AKI: Acute kidney injury; EUA: Emergency Use Authorization

Niyad: Solving the Challenges in CRRT

- Kidney Disease Improving Global Outcome (KDIGO) clinical practice guidelines for AKI recommend using anticoagulation during RRT
- **Challenge: There is no suitable anticoagulant available**
- **Solution: Niyad provides anticoagulation without the shortcomings of heparin or citrate**
  - No contraindications for Niyad
    - Can be used in patients at risk of bleeding, whereas heparin can not
    - Can be used in patients with liver failure, whereas citrate can not
  - Fewer filter changes, less blood loss, fewer transfusions
  - **Reduced doctor and nursing time** (the decision makers in selecting an anticoagulant)



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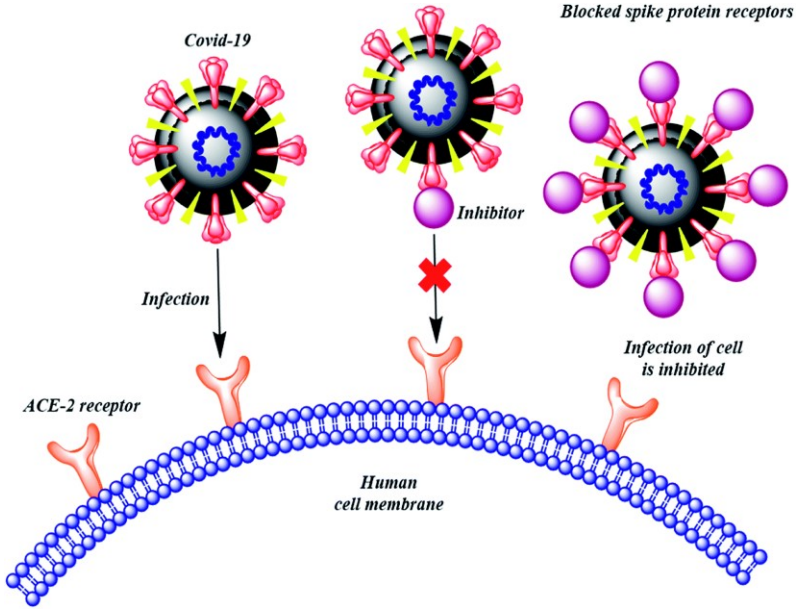
RRT: Renal replacement therapy

FDA Granted Breakthrough Designation to Niyad

- FDA granted Breakthrough Device Designation for Niyad.
- FDA grants Breakthrough Designation to devices that show **improved efficacy** for the treatment of **life-threatening conditions.**
- Niyad is expected to provide an option for anticoagulation that does not exist today and is an improvement over the standard of care, especially in patients undergoing CRRT that cannot tolerate heparin or are at a higher risk of bleeding.
- Breakthrough Designation has many benefits such as expedited review by FDA.
- More importantly, it allows for **CMS reimbursement of up to 65%** of the cost over the existing DRG. See also the TPNIES (Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies).
- The program is designed to **encourage adoption of new technology immediately** upon commercialization and should greatly enhance the value of both Niyad and Lowell Therapeutics.

LTX-608 – Drug Indication

- LTX-608
  - TMPRSS2 inhibitor of virus fusion
  - Inhibits tryptase, mediator of vascular leak syndrome, which may prevent ARDS
  - Modulate pro-inflammatory cytokines
- Patient populations:
  - Acute respiratory distress syndrome (ARDS); Disseminated intravascular coagulation (DIC); Acute pancreatitis (AP)
- Clinical Strategy
  - Conduct IND enabling studies
  - Complete Phase 2 trial for ARDS in COVID-19 patients, then expand to other etiologies such as influenza & sepsis



Source: DOI: 10.1039/D0RA04795C

TMPRSS2: Transmembrane protease, serine 2

Summary

- Niyad provides anticoagulation for patients in the ICU on an artificial kidney machine without the challenges and safety issues of current standard of care, i.e., Heparin and Citrate
- FDA agreed to regulate Niyad as a Device and granted **Breakthrough Designation**
  - Expedited development, **CMS reimbursement of 65% over existing DRG in ICU**
  - Eligible for **TPNIES add-on payment** for outpatient clinic
  - FDA confirmed endpoint
- WW market is $1.6 billion
  - $300 million (US) for Niyad
  - $1.3 billion for ARDS (WW)
- Experienced management team and advisory board with outstanding operational expertise

DRG: diagnostic research group used for billing.