# Aquadex® Ultrafiltration

*Presented by John McInnes, Counsel, Arnold & Porter*

*Consultant to Nuwellis*

# Issue Summary

- Therapeutic ultrafiltration (CPT code 0692T) is an apheresis procedure through which plasma water is removed from the blood using the Aquadex SmartFlow System.
- 0692T is currently assigned to APC 5241 Level 1 Blood Exchange and Related Procedures but differs from the transfusion procedures assigned to this APC both clinically and in terms of resource use.
- Nuwellis asks the HOP Panel to recommend that CMS reassign 0692T to APC 5242 which includes other apheresis procedures that are similar clinically and in terms of cost to therapeutic ultrafiltration.

# Definition of Hypervolemia (Fluid Overload)

**Hypervolemia**, also known as **Fluid Overload**, is the medical condition where there is too much fluid in the blood. Fluid volume excess in the intravascular compartment occurs due to an increase in total body sodium content and a consequent increase in extracellular body water. Many times patients are resistant to diuretics, where fluid volume is uncontrolled, necessitating the need for **isotonic plasma water** to be removed.

## Chronic conditions leading to Hypervolemia:

The mechanism usually stems from compromised regulatory mechanisms for sodium handling as seen in **congestive heart failure (CHF)**, **kidney failure, post-cardiac surgery (CABG), sepsis** and **liver failure**. It may also be caused by excessive intake of sodium from foods, intravenous (IV) solutions and blood transfusions, medications, or diagnostic contrast dyes.

# Definition of Apheresis

**“Pheresis” means subtract or take away**

**“Apheresis” means to separate the Blood**

**Definition: Apheresis**

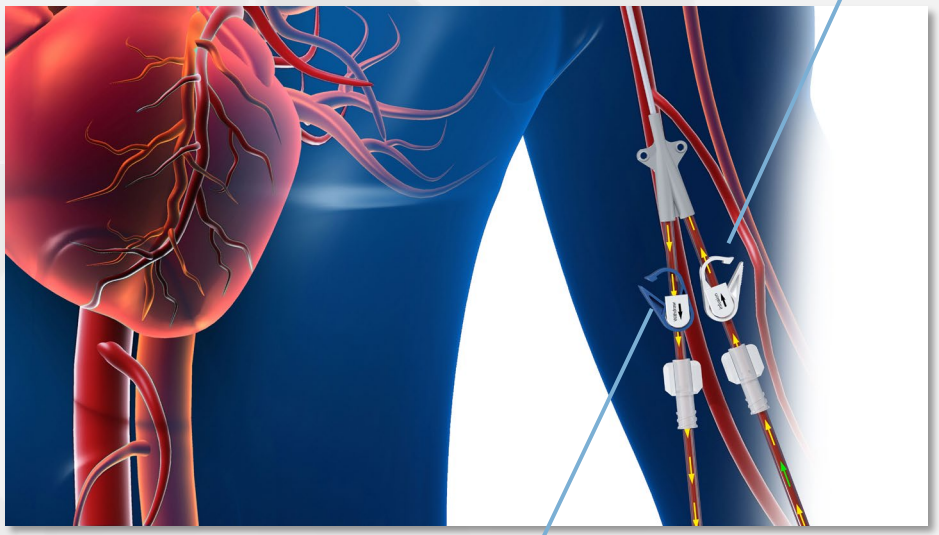
*“Is the extracorporeal process of withdrawing blood, filtering something out of the blood and returning the filtered blood back into the body”*

**Aquadex restores fluid balance by removing isotonic fluid (Plasma Water) from the blood while returning the blood back to the body through the Aquadex pump**

**More complex procedure than blood transfusion**

# How the Aquadex System Works

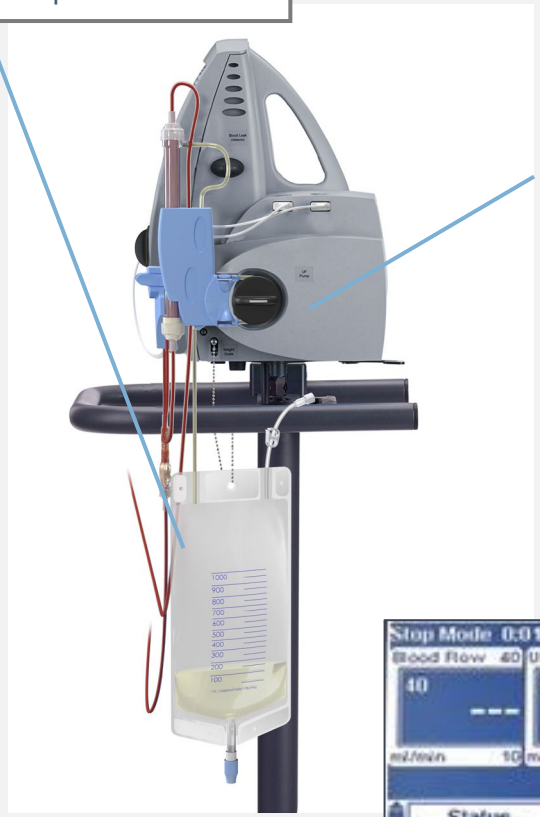
## Predictable and Precise Fluid Removal



1 Blood is taken from the patient via the withdrawal line


2 The blood is pushed through the filter by the blood pump

(0-40 ml per minute)



3 The ultrafiltration pump withdraws isotonic fluid across filter membrane using negative pressure

Hematocrit sensor monitors preset hematocrit limits

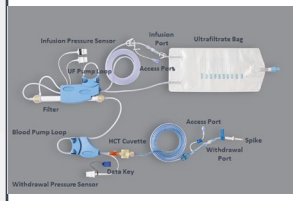
4 Ultrafiltration pump can pull 0-500 ml of fluid per hour


5 Filtered blood returns to the patient via the infusion line



nuwellis
Restoring Fluid Balance, Transforming Care®

# Aquadex cost vs Apheresis cost comparison

|  **Aquadex (0692T)** | **vs** | **Apheresis (36514)** |
|---|---|---|
|  Machine = $41k<br>Stand = $1,250<br>Circuit = $1,040<br>dELC Catheter = $450<br><br>**Total = $43,940** | **Cost** | ~$50k = Machine<br>~$1,500 - $3,000 = Disposables<br><br>**~$51,500 - $53,000 = Total** |
| **4-7 hours** | **Time of treatment** | **2-4 hours** |
| Inpatient or Outpatient | **Site of service** | Inpatient or Outpatient |
| Monitor and treatment | **Nursing effort** | Monitor and treatment |

# Issue Summary

- 0692T is currently assigned to APC 5241 Level 1 Blood Exchange and Related Procedures but differs from the transfusion procedures assigned to this APC both clinically and in terms of resource use.
- Apheresis codes including 36514 are assigned to Level 2 (APC 5242).
- Nuwellis asks the HOP Panel to recommend that CMS reassign 0692T to APC 5242 which includes other apheresis procedures that are similar clinically and in terms of cost to therapeutic ultrafiltration.

# Indications for use

**The Aquadex SmartFlow® System is indicated for:**

Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics.

All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies.






nuwellis®
Restoring Fluid Balance. Transforming Care.®