



## Managed Care Dossier



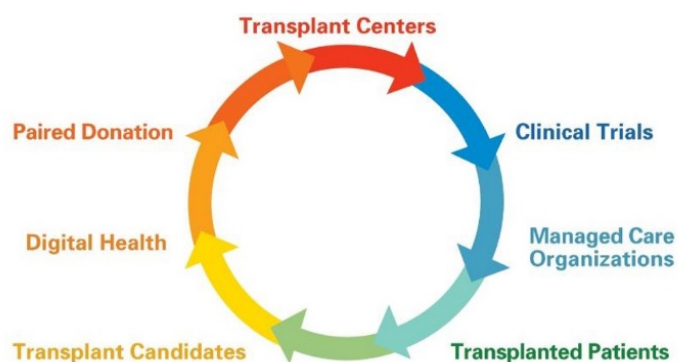
## Section 1: Introduction

BiologicTx was founded as the first, solely focused infusion and pharmacy provider of biologic and oral transplant therapy management. Since then, BiologicTx has expanded its services to integrate transplant therapies paired with digital health technology, providing a complete representation of the patient's response to therapy. We offer a broad range of specialty infusion services in transplant, neurology, hematology, and immunology.

### Leader in Transplant Services

BiologicTx is led by dedicated professionals striving to advance desensitization, immunosuppressive, and rejection treatments, worldwide, to achieve progressive and favorable patient outcomes.

We specialize in solid organ transplant services and provide the highest quality patient care. We deliver efficient, start to finish services, beginning with the insurance authorization process to establish therapeutic services in the home and clinic. We act in concert with the transplant center medical team to provide a consistent stream of information on the patient's response to therapy. Through this integrated service offering, we help to improve patient outcomes and reduce cost for both public and private payers.



### Therapeutic Expertise

BiologicTx specializes in the administration of intravenous biologic therapies. In the pre-transplant patient segment, desensitization therapy is administered to patients in an effort to increase the pool of patients eligible for transplant. This reduces the overall health plan budget for the transplant segment by improving time-to-transplant at the plan level. After successful transplant, BiologicTx provides patients with comprehensive management of their oral immunosuppressive regimen, ensuring required treatment protocols are followed and providing necessary biologic interventions.

### Experience the Difference

The BiologicTx management team has unparalleled transplant therapy expertise in:

- Desensitization Therapy: Provided for highly sensitized, pre-transplant patients, by administering IVIg and other biologics, resulting in increased likelihood of successful transplantation
- Antibody Mediated Rejection (AMR): Provided for solid organ transplant recipients
- Supportive Therapies: Provided for solid organ recipients to treat infection, heart failure, CMV, and BK with antivirals and inotropes
- Immunosuppressive Medications: Dispensing, management, and compliance on a national scale

## Section 2: Payer Benefits Summary

### Desensitization Therapy

A significant impact on transplant success is sensitization. In a study by Vo et al<sup>1</sup>, published March 2013, the authors concluded that desensitization therapy is clinically effective and cost-effective, with financial savings, as well as an estimated 17.6% greater probability of 3-year survival associated with desensitization versus dialysis alone.

Hospital or transplant center waitlists consist of 32% of patients that have a need for desensitization. This greatly limits the access to transplantation for this population. In a study by Montgomery et al<sup>2</sup>, the authors recognize this statistic as a serious public health problem and that 98% of treated patients with desensitization progressed to transplantation.

However, the hospital reimbursement is very limited or non-existent for DSA treatment. Hospital cannot be reimbursed for in-patient desensitization services due to Medicare Part B and DRG issues, resulting in a significant per patient cost. In addition, hospitals are not properly staffed to provide a desensitization program.

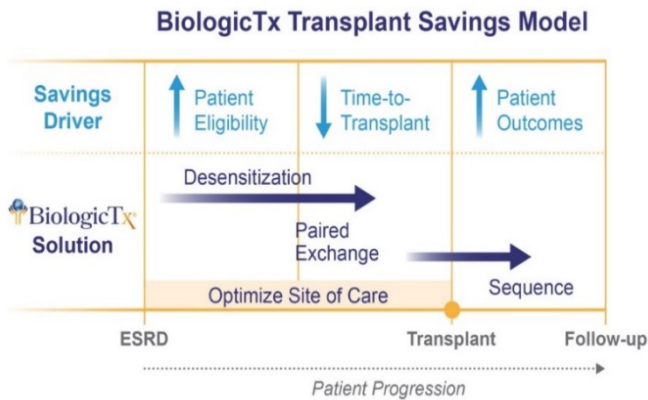
BiologicTx offers seamless reimbursement coverage for the members and for Managed Care Organizations with the ability to appropriately bill Medicare Part D for out-patient services while offering more cost efficient services in the home setting.

### Budget Impact

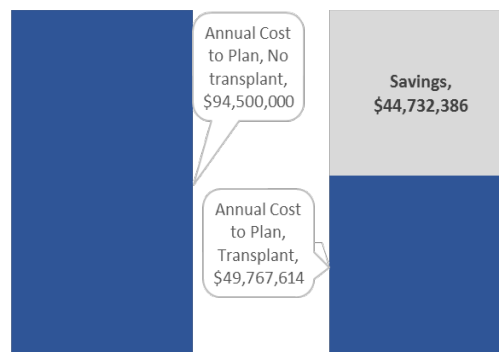
Results of a three year transplant clinical outcomes trial using BiologicTx services were very favorable, as the median time to transplant was 3.8 months following start of IVIg desensitization. Because the average length of time to transplant is estimated at 53 months, this represents huge benefits both clinically and financially. When analyzing the health plan's financial commitment for a patient starting dialysis treatment, the first 33 months are critical, as this is the time that the plan is responsible for the majority of treatment costs prior to Medicare coverage. The cost for dialysis treatment is approximately \$25 thousand per month, of which the payer is responsible for 80%. Over a 33 month period, the cost of a patient requiring dialysis is approximately \$660 thousand.



Since the cost of treating a patient with a successful transplant becomes substantially lower after the first year post-transplant, the cost of treatment for 33 months decreases by almost 50% and demonstrates a 33 month savings of over \$300,000 for every patient that is desensitized promptly to allow for earlier transplant. The projected annual savings per 1 million plan members is over \$44 million, or a PMPM savings of close to \$4 dollars.



#### Desensitization savings per 1M member plan



#### Current Clinical Outcomes

In an ongoing desensitization study operated by BiologicTx, an effective transplant rate of 33% was achieved, and the median time to transplant was 3.8 months following IVIg desensitization. The 12-month rejection rate in those with >1 year of follow-up was 6%. This is a significantly lower percentage than the 12-month rejection rate of 10%, as reported in the 2012 OPTN/SRTR Report. In comparison to other desensitization program results, it is much lower than the average rate of 26% reported across major high dose IVIg desensitization programs.

## Transplant Center of Excellence

Our exceptional experience in transplant management offers Managed Care Organizations a collaborative partner to treat their members and coordination of care within the provider network and transplant centers. The success of this collaboration and BiologicTx Paired Donation significantly reduces the time-to-transplant.

## Care Management

BiologicTx has unparalleled technology capabilities in the industry. BiologicTx Sequence offers therapeutic data management that allows coordination of transplant services within your provider network.

## Site of Care

BiologicTx's services align with patient outcomes and reduced cost to the health care system. Highly coordinated services developed around proven protocols help increase the transplant center's ability to successfully transplant patients, reducing the high cost associated with complications and maintaining the health of patients. BiologicTx can also reduce the length of hospital stays by moving the services to the home or office setting while maintaining coordinated care with the transplant center.

## Section 3: Biologic Transplant Medications

### Therapy Offerings

- Cytogam
- Eculizumab (Soliris)
- Thymoglobulin
- Hizentra
- IVIg
- Belatacept (Nulojix)
- Oral Immunosuppressives
- Antibiotics
- Bortezomib (Velcade)
- Rituximab (Rituxan)



## Unparalleled Therapeutic Expertise

BiologicTx's primary objective is to reduce antibodies enabling patients to receive transplantation, minimize rejection, and reduce overall healthcare expenditures by significantly reducing dialysis days.

## Service Leading Solid Organ Transplant Centers

BiologicTx services over 100 transplant centers across the United States.

## Section 4: Transplant Services

### Nursing Services

Our exceptional nursing staff provides nationwide coverage, and are trained specialists in the safe administration of IVIG in the home. The RN will provide one on one patient visits during entire infusions while the infusions are scheduled between dialysis days. BiologicTx's staff can accommodate evening and weekend infusions with the capabilities of peripheral and mid-line placement and center line access.

Our experienced Transplant Nurse Liaisons work with centers in your network to assist in protocol development, the coordination of patient contact and consents, the providing of monthly patient data outcome reports, the arranging of PRA samples to be sent to HLA Labs, and they meet monthly with the team while providing overall medical and administrative patient management.

A highly qualified infusion nurse administers the desensitization treatment prior to dialysis, minimizing side effects and adverse reactions due to fluid volume. BiologicTx uses a targeted approach by prescreening patients MFI's/DSA's with the HLA laboratory. This significantly increases favorable patient outcomes and lower cost.

BiologicTx also assists in reducing the length of stay and eliminating costly therapies by developing a protocol with the hospital, whereby, once a patient is admitted for Acute/Chronic AMR, they can be quickly discharged and treated at home in an outpatient setting.

BiologicTx provides the expertise in desensitization therapy and program development that will provide patient criteria, protocols, and patient selection to produce optimal outcomes and reduce risk with no impact SRTR scores.

There are no additional costs associated with BiologicTx's specialized services. Our authorization team works directly with your case managers and other payers, obtaining approval for appropriate treatments.



Advancements in Biologic Post Transplant Therapeutics	
<b>Outpatient for de novo and conversion patients</b>	<ul style="list-style-type: none"> <li>• Belatacept (Nulojix)</li> <li>• IVIG</li> </ul>
<b>Hyper Acute Rejection, PNH and aHUS</b>	<ul style="list-style-type: none"> <li>• Eculizumab (Soliris)</li> <li>• Others:               <ul style="list-style-type: none"> <li>• Hizentra</li> <li>• Thymoglobulin</li> <li>• Bortezomib (Velcade)</li> <li>• Cytogam</li> <li>• Rituximab (Rituxan)</li> </ul> </li> </ul>

### Section 5: Clinical Trials in Transplant

BiologicTx is currently engaged in clinical trials that address the spectrum of challenges faced by transplantation, involving biologics from immunology to oncology, advancing the science through aggressive immune modulation protocols.

We are committed to providing the means, data, and support necessary to advance the use of biologics effectively within solid organ transplantation. Our goal is to enhance the safety and quality of the therapies prescribed to patients and reduce overall healthcare expenditures for the nation. We accomplish this by aiding targeted research with a direct impact in paired donation desensitization, living and deceased donor desensitization, preemptive DSA, and acute/chronic biologic therapeutic interventions.

We provide the following clinical trial services directly through one of our strategic partners:



- Transplant focused Clinical Research Organization (CRO Services)
- Trial design consultation
- Research coordination
- Collection of data
- Drug and administration
- Publication strategy and assistance
- Financial sponsorship and support

## Section 6: Forward Thinking Technology

### Discovery 2 Life™ Platform (D2L)

BiologicTx operates a leading digital health platform designed to guide and support hospitals, clinicians, and patients throughout the organ transplant continuum. D2L supports the organ transplant process, including organization of data associated with enrolling a transplant candidate into a desensitization therapeutic program. From a single data source, all key information is organized and available to all key stakeholders.

### BiologicTx Sequence™

BiologicTx Sequence is a multi-factor authenticated therapeutic data management and analytics program that is encrypted and HIPAA compliant. This systematic database combines drug therapy interventions administered by BiologicTx with transplant center tissue typing, DSA information, and patient specific data. The results of this data will provide the transplant center clinician with a global picture of the therapeutic impact and efficacy of prescribed medications along with lab data, graphs, stratification, data mining capabilities, and full PDF reporting features for print or scanned to the patient's EMR.

In addition to individual patient information, the clinician will be able to view and evaluate their own transplant center's responses to various therapies for all organ types with desensitization, AMR, infection, and immunosuppression provided by BiologicTx. The benefit can impact living and deceased donation outcomes as well as BiologicTx Paired Donation™ volume.

BiologicTx has the capability to manually collect, or interface directly with, the transplant center information systems for all participating centers.

BiologicTx Sequence Help Desk provides technical and clinical support for system access, data integration, retrieval and questions.

BiologicTx Sequence will overcome the challenges that are currently faced by clinicians in data collection, aggregating lab results and interpretation of patient's overall clinical progress. BiologicTx will integrate the therapeutic information with transplant center's participation in this project to better understand the efficacy of transplant treatments.





## Features of BiologicTx Sequence

- Transplant Center Dashboard
  - Patient referral, authorization, and treatment status
  - Volume of patients on service, by therapy
  - Time to transplant
  - Post-transplant compliance management
  - BiologicTx Paired Donation patients receiving therapy
- Recipient Dashboard
  - Cumulative overview of patient therapy administered, clinical profiles, and laboratory data
- Recipient Information
  - Patient and clinical profile
  - Laboratory data associated with therapy administered
  - HLA Data (tissue typing, PRA, cPRA, DSA)
  - Transplant procedure
  - Listing information
  - Living, deceased, or paired donation donor data
  - Adverse event reporting
- Donor Information
  - Donor data by transplant center
  - Donors associated with the BiologicTx Paired Donation program
- BiologicTx Sequence Help Desk
  - Expert technical and clinical support
- Custom Reports
  - Aggregated transplant center data reports

## BiologicTx Paired Donation Program

BiologicTx recognizes the need to develop a paired donation program to achieve the goal of being a complete kidney transplant provider. The introduction of the BiologicTx Paired Donation Program into our list of transplant services makes BiologicTx a unique and valuable service provider throughout the transplant patient's full spectrum of care.

The new paradigm for Kidney Paired Donation (KPD) is to include compatible pairs to increase transplant opportunities for incompatible pairs and find better matches for compatible pairs. This process is easier to accomplish in a single-center setting. The BiologicTx Paired Donation program offers our advanced software matching system to transplant centers as a means to accomplish this and expand their living donor programs. As a single-center KPD, data entry and match runs can be done at any time to evaluate potential pairings without the restriction of waiting until pairs have completed an evaluation, as is necessary in a national system.



In addition, a single-center KPD helps minimize legal, logistical, insurance, timing, and cost concerns attributed to national pairing programs. However, the BiologicTx KPD program also offers the option of participation in regional/national pairings.

In order to identify possible matching pairs, BiologicTx acquired Silverstone Matchgrid. Matchgrid is a proprietary, HIPAA compliant, cloud-based software that utilizes advanced matching and optimization algorithms with the ability to evaluate all potential 2-, 3-, 4-, 5-, and 6-way combination within minutes. Matchgrid also optimizes the number of transplants for a given pool of donor/recipient pairs, ensuring the maximum number of transplants for the most difficult people to match.

Additional capabilities of Matchgrid include:

- Ability to add non-directed donors and compatible pairs
- Ability to set acceptable individual MFI ranges and avoids
- Ability to set clinical preferences
- Allows MFI and cPRA tracking through BiologicTx Sequence
- Sub-type matching
- Capability to integrate with HLA labs to upload information

The BiologicTx Paired Donation team is a highly specialized group of professionals supporting the transplant center's needs by initiating a program or adding to an existing system. The support team includes:

- Medical and Scientific Review Board, overseeing all regional and national pairings
- Technology Experts that upgrade and advance software capabilities
- Clinical Transplant Support Staff that provide tools and assistance for exchanges, professional and patient/family education, desensitization identification with protocol assistance, and follow up

## **Section 7: BiologicTx Specialty**

Our specialty pharmacy can support the complete spectrum of transplant medications, from oral medications to in-home IVIg therapy.

### **Complete IVIg Service**

IVIg is provided nationally with experienced nurses that must pass a stringent selection process by our nursing department and must meet our criteria for proper IVIg infusions. Our clinical staff is proficient in starting IVIg at home when first doses in a medical setting are not necessary which creates savings for payers. Nurses provide one on one visits, and will stay with the patient during the entire infusion. All visit notes and laboratories will be made available via BiologicTx Sequence.

BiologicTx Specialty has access to all brands at very high volumes with a trained pharmacist that can provide the correct brand of IVIg based on patient clinical presentation. In order to ensure pedigree, all IVIg is purchased either directly from the manufacturer OR from a manufacturer approved distributor to ensure purity and proper handling.

Our trained authorizations department is skilled in obtaining approval for off-labeled use of a medically-necessary/medically-accepted drug for autoimmune diseases and transplant services.

All ancillary supplies and equipment are delivered along with the IVIg for proper administration. Delivery of drug/supplies and nursing visits are all scheduled around the patients' request.

Emergency 24/7 days per week on call pharmacy and nursing coverage is available in all regions.

### Neurology

Treatment of neurological disorders with use of IVIg has become the standard of care in many neurological practices throughout the United States. Recent studies have determined that IVIg was well tolerated in long term use and was just as effective as Plasmapheresis in treating various neurological conditions.

The neurological conditions are as follows:

- Myasthenia Gravis (Acute Severe or Deteriorating)
- Lambert – Eaton Syndrome
- Dermatomyositis
- Multiple Sclerosis (Relapse Rate)
- Kawasaki
- Stiff – Mans syndrome

### Hematology

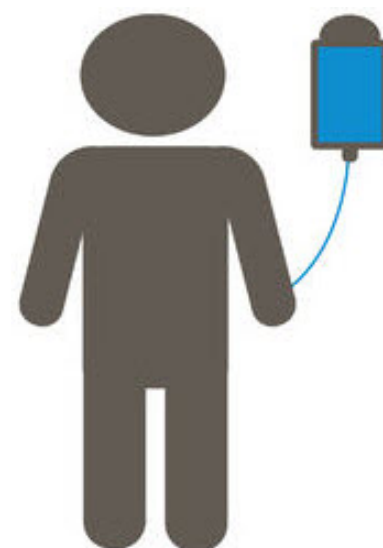
BiologicTx has been recognized by the state of New Jersey as a Hemophilia provider and has been approved by the Hemophilia Association of New Jersey (HANJ).

### Immunology

Our experience in managing Primary Immune Deficiency Disease (PID) runs deep. Our highly qualified clinical staff has serviced well over 1,000 PIDD patients over a 10-year period.

Most Common Types of PIDD:

- IgG subclass
- Selective IgA Deficiency
- Common Variable Immunodeficiency (CVID)
- Severe Combined Immunodeficiency (SCID)
- Chronic Granulomatous Disease (CDG)
- Wiskott – Aldrich Syndrome



## Parental Nutrition

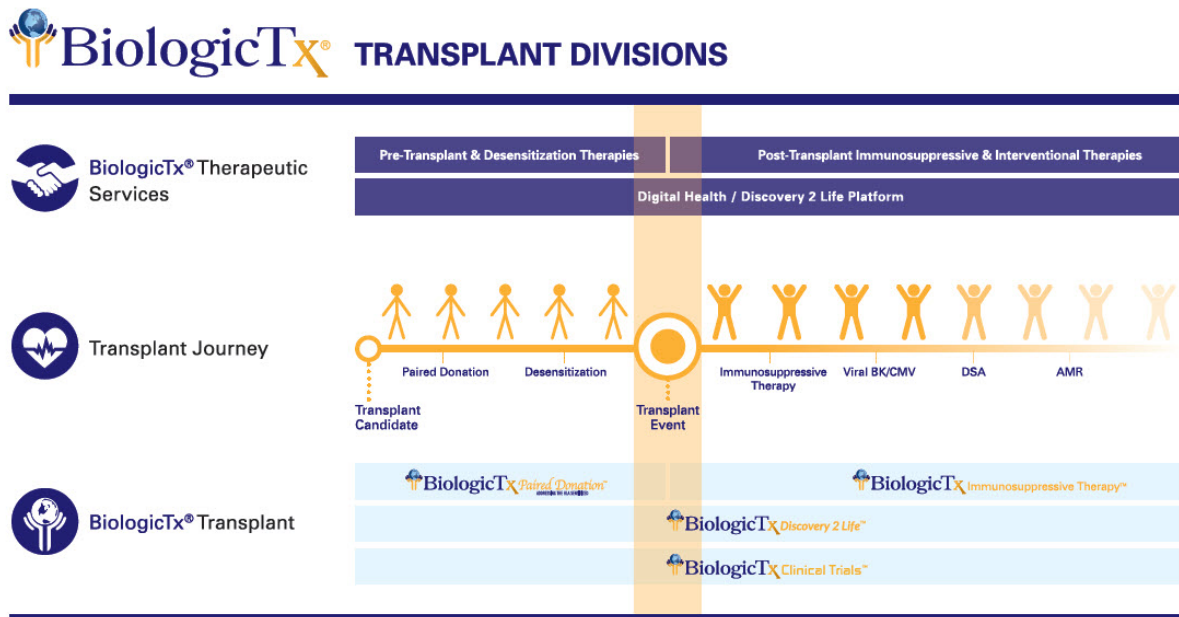
BiologicTx Specialty has created this specialty division to provide high cost and complicated home infusion therapies through a more efficient process that will enable quicker turnaround times post hospital discharge and provide a better overall experience than what is currently offered today. We offer personal, one-on-one service that will make patient transition from hospital to home effortless.

## Accreditation

BiologicTx is accredited by the ACHC for Infusion Pharmacy and Nursing Services and is currently in process for URAC accreditation (full URAC accreditation is expected in first quarter of 2016).\*

## Conclusion

At BiologicTx, our founding mission and long-term commitment is to lead, manage, and care for transplant patients with the highest level of support, education, and integrity. We provide services that support the patient through every stage of their organ transplant, both before and after their new organ has been transplanted. Our pre-transplant therapeutic interventions, combined with our post-transplant management of immunosuppressive medication regimens, ensures patient compliance and adherence to their prescribed treatment.



\*ACHC Accreditation – Infusion Pharmacy & Nursing – Totowa, NJ Location