



Medical/Clinical Necessity Form

POLICY: It is the policy of FusionIV Pharmaceuticals dba AXIA Pharmaceutical to conduct its business in compliance with applicable federal, state and local laws and regulations, and to adhere to the highest ethical standards.

STANDARD: It is the standard of FusionIV Pharmaceuticals dba AXIA Pharmaceutical to provide only manufactured sterile injectable products which are not essentially copies of one or more approved drugs. However, there are cases in which drugs are determined to be medically/clinically necessary which may seem to be in conflict with this policy. "Medically/clinically necessary" is defined as:

- Consistent with generally-accepted standards in the field of treatment, or other discrete clinical discipline, providing a designated effect;
- Are reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Are appropriate to the condition or need set being treated;
- Require the specific level of care or expertise being proposed;
- Are individualized based on the assessed needs of the individual;
- Are provided in the most integrated setting for the given need(s) being addressed;
- Are not conducted for the convenience of the provider, the person receiving the service, family members, payers, or any other parties.

Manufactured sterile injectable products that are "medically/clinically necessary" may be required when:

- Best practice clinical intervention has not been effective;
- Differential diagnosis is indicated to develop a more effective treatment plan;
- The individual has a medical or neurological condition and has been referred by a physician for further assessment after being evaluated by the MD;
- An individual presents with concerns regarding specialized services.

Such products manufactured by FusionIV Pharmaceuticals dba AXIA Pharmaceutical cannot be billed to insurance using an NDC for a similar product produced by any other entity. FusionIV Pharmaceuticals dba AXIA Pharmaceutical will not be held liable for issues arising from how products are billed.

Reason for being medically/clinically necessary (please check all that apply):

- ☐ Change in administration
- ☐ Change in strength
- ☐ Addition/removal of excipient
- ☐ Is on FDA Drug Shortage list
- ☐ Is not otherwise available or cannot be easily obtained through other means
- ☐ other (specify):

My signature on this document signifies that as of _____(date), I, _____, hereby certify that the product(s) requested is/are medically and/or clinically necessary despite being related to one or more approved drugs, and I do not hold FusionIV Pharmaceuticals dba AXIA Pharmaceutical responsible for any matters related to its/their billing.



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☐ **Changes to Existing**

Please provide License, DEA, and NPI Numbers for All prescribing Physicians

Name	License	DEA	NPI

Special Shipping Instructions

[illegible]



AXIA
P H A R M A C E U T I C A L

Title:			
Product:			
Phone:	Fax:	E-mail:	
Shipping Address:			
City:	State:	Zip Code:	
Federal Tax Id or SS #:			

Shipping Policy

Thank you for choosing AXIA. Below are the terms and conditions that constitute our Shipping Policy.

Shipment Processing Time

Orders are generally processed within 1-2 business days.

Note: To ensure orders are processed the same day, the order must be received by 12 pm PST.

Shipping Rates & Delivery Estimates

To ensure the quality of our products is not compromised, all orders are shipped via overnight delivery.

Shipment Method	Estimated delivery time	Shipment cost
Standard Overnight (Non Refrigerated Items)	1-2 business days	\$20.00
Standard Overnight (Refrigerated Items)	1-2 business days	\$25.00

Missed Deliveries: Should your facility not be able to accept a scheduled delivery, the following charges will apply:

Refrigerated Items

Due to strict FDA regulations, all refrigerated items returned to our facility must be discarded and reprocessed. Customers will be billed **50%** of the order cost for replacement orders, along with standard shipping rates.

Non Refrigerated Items

All items returned to our facility due to non-delivery will be reshipped at the customer's expense.

Return Policy: No returns will be accepted for medication.

Name:		Title:	
Signature:		Date:	