TAP PHARMACEUTICAL PRODUCTS INC.
PATIENT ASSISTANCE PROGRAM
PO Box 66586
St. Louis, MO 63166-6586

Instructions

The TAP Pharmaceutical Products Inc. Patient Assistance Program ("the Program") provides Lupron Depot (leuprolide acetate for depot suspension) at no charge to patients in need. The need of a patient is determined according to guidelines established by TAP Pharmaceutical Products Inc. that are based on federal standards. The Patient Assistance Program may be changed or discontinued at any time in the sole discretion of TAP Pharmaceutical Products Inc.

Enrollment Process: Call 1-800-830-1015 to obtain an application for the Patient Assistance Program for Lupron. An application will be promptly faxed to the physician's office or mailed to the patient.

Please complete all applicable sections. If an item does not apply, please mark N/A on the line. Incomplete applications will not be processed.

Section 1 – Physician Information

This section must have all physician information completed and signature of the physician is required. An original prescription must be included with the application.

Section 2 – Patient Information

This section must have all patient information completed. Patient must list all medications they are currently taking and list any allergies or medical conditions.

Section 3 – Patient Insurance Information

"Enrolled" or "Not Enrolled" must be filled out under all three insurance questions.

Private Insurance – If you have private insurance, please indicate if injectables are covered by benefits.

Medicare – If enrolled is checked, please mark appropriate box (Part A, B or D)

Medicaid/Public Assistance - If you have Medicaid/Public Assistance, please indicate if injectables are covered by benefits.

Section 4 – Household Financial Information

Patients must list all sources of income. To assess a patient's need, **financial documentation is required**. Applications submitted without the proper financial documentation will not be processed and will be returned to the patient with a letter specifying the information that is missing. Acceptable documentation means the patient's most recent federal income tax return. If the patient did not file a federal income tax return in the last sixteen (16) months then please submit each of the following that applies to the patient:

- Yearly benefits statement (SSA-1099)
- IRS Form 4506T (Request for Transcript of Tax Return/Verification of Nonfiling)*
- IRS Telefile Worksheet
- W2 Tax statement
- Social Security, Pension, or Railroad Retirement statements (SSA-1099)
- Statements of interest, dividends or other income (1099-INT, 1099, 1099T, 1099-DIV)

*Patients can get a copy of the IRS Form 4506T by calling a Customer Service Representative at 1-800-830-1015.

Section 5 – Patient Signature (Required)

Patient's signature is required for eligibility determination.

Submission of Application, Approval and Shipment of Medication: Once the enrollment application is complete, physicians may fax the application, financial documentation, and an original prescription to 1-866-884-5909 or patient can mail all documents to the address indicated above. A TAP Program specialist will evaluate the application using the pre-established program guidelines to determine the patient's eligibility. If the patient is approved for participation in the program, an approval letter will be mailed to the patient and physician confirming the patient's acceptance into the program and a supply of Lupron will be shipped to the physician's office within 4 - 5 business days. If an application is denied, a denial letter will be mailed to the patient and to the physician.

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Patient Assistance Program
PO Box 66586
St. Louis, MO 63166-6586
1-800-830-1015 Phone
1-866-884-5909 Fax

Please attach an original prescription.

Available Medication:

Lupron Depot 3.75 mg®
Lupron Depot 7.5 mg®
Lupron Depot 3 month 11.25 mg®
Lupron Depot 3 month 22.5 mg®
Lupron Depot 4 month 30 mg®
Lupron Depot-PED 7.5 mg®
Lupron Depot-PED 11.25 mg®
Lupron Depot-PED 15 mg®
Lupron Depot (leuprolide acetate for depot suspension)
Lupron Depot –PED (leuprolide acetate for depot suspension)

SECTION 1 PHYSICIAN INFORMATION

Physician Name		DEA/State License #
Address		City, State & Zip Code
Office Ph. Number (	Office Fax Number (	Office Contact person

I certify that the patient(s) named on this form will receive Lupron Depot free of charge. The product ordered hereunder is medically necessary for the patient(s), and that I will be supervising the patient(s) treatment. These patient(s) have demonstrated medical and financial need for assistance. I certify that the medication provided under this Program will only be used for the patient named on this form. It will not be sold, otherwise distributed or returned for credit, and neither patient(s), nor any third party payer, (including, but not limited to, Medicare or Medicaid, or any other federally funded healthcare program) was or will be charged for this product. I understand that eligibility for this Program is subject to TAP's approval and the patient's continuing compliance with all eligibility requirements as established by TAP. I agree to allow TAP, or its authorized agent(s), to review the medical, financial, and insurance records of this patient at any time for the purpose of verifying the patient's eligibility for the program and the patient's receipt of any product provided to him or her under the program. I have received a signed Patient Authorization to Disclose Protected Health Information from the above-named patient. This information is true and accurate to the best of my knowledge.

Physician's signature (**Required**) Date

X

SECTION 2 PATIENT INFORMATION

Name	SSN/ID Number	Date of Birth
Address	City, State & Zip Code	
Daytime Phone (	Legal US Resident ☐ Yes ☐ No	Number of people in household (including self): (Circle One) :

List any patient allergies	List any current medications	List any medical conditions

SECTION 3 PATIENT INSURANCE INFORMATION

Private Insurance	Medicare	Medicaid/Public Assistance
☐ Enrolled** ☐ Not Enrolled **If enrolled, are injectables covered by pharmacy benefits? ☐ Yes ☐ No	☐ Enrolled ☐ Not Enrolled ☐ Part A ☐ Part B ☐ Part D	☐ Enrolled** ☐ Not Enrolled **If enrolled, are injectables covered by benefits? ☐ Yes ☐ No

SECTION 4 HOUSEHOLD FINANCIAL INFORMATION

You must list all sources of Total Monthly Household Income and attach a copy of your most recent U.S. income tax return (i.e., IRS Form 1040, 1040A, 1040EZ, 4506T, and 1099). **If you did not file an income tax return, you may complete and submit an IRS form 4506T (Request for Transcript of Tax Return/Verification of Nonfiling).** Total Monthly Household Income includes gross monthly income of patient, spouse and others living in household. You must include salary, pension, Social Security income, SSI-Supplemental Security Income, Social Security Disability and Unemployment Compensation.

Salary/Wages	$_____	Social Security	$_____	Child Support/Alimony	$_____
Disability	$_____	Pension/ Retirement	$_____	Unemployment/ Work Comp	$_____

Gross Monthly Income **Total: $ _____**

SECTION 5 PATIENT SIGNATURE

USE AND RELEASE INFORMATION FOR PATIENT ASSISTANCE PROGRAM ("PROGRAM")

I allow my health care providers, physicians, any specialty pharmacy or specialty distribution center, third party service provider, or my health plans (collectively, Providers), if any, to use, share, and disclose my protected health information (PHI) as requested by the Program. This PHI includes my name, information from my medical record, health plan information and financial information. My PHI will be given to TAP Pharmaceutical Products Inc. ("TAP"), AmeriCares and any other contractors or partners that help with the Program, and the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services or any agent or agents thereof ("CMS"). The use and disclosure of my PHI are so that I may apply and, if approved, receive Lupron from the TAP Program. My information will be treated confidentially to the extent required by law. I understand that if my PHI is disclosed, federal privacy laws may no longer protect the information from further disclosure. This authorization expires one (1) year from the date of my signature below. I can choose not to sign this form or cancel this authorization at any time. If I want to cancel this authorization, I will be required to send a written request to TAP at the address on this form. This cancellation will apply to Providers when my cancellation notice is received by those Providers. My cancellation will not apply to PHI already obtained by Providers if they have already used or disclosed my PHI, or acted in reliance on my authorization. I understand that by not signing this form, my health care treatment outside the TAP Program, health plans' payment for health care, or my ability to get benefits from health plans will not be affected. Signing this form is not a guarantee that I will be able to receive Lupron from the TAP Program. I acknowledge that I have been provided a copy of this authorization.

I certify that I do not have any insurance coverage for injectable medication. I agree that I will contact TAP at the address on this form if any of the information on this form regarding coverage for injectable drugs changes. My signature certifies that the information on this form is true and correct. I consent to the release by my Providers of my medical information pertaining to the TAP Program to be used for program authorization purposes. I authorize TAP and its agents and assignees to use the information on this application to process the request for medication from the TAP Program and further authorize the use of my Social Security number for identification purposes and record keeping. I also authorize TAP and its agents and assignees to provide the information on this application, including my social security number, to CMS. I understand TAP reserves the right at any time without notice to modify or discontinue this program and its eligibility criteria. I understand that TAP may modify or discontinue this Program at any time. I understand that my prescribing healthcare provider is responsible for choosing which prescription products are right for me, and that TAP is not responsible for verifying my medical condition or my prescribing healthcare provider's selection of products.

Patient or Personal Representative signature (**Required**) Date

X

Personal Representative's relationship to Patient:

Notice to all parties completing this form. It is fraudulent to fill out this form with information under this program you know to be false or to omit important facts. Criminal and/or civil penalties can result from such acts. The TAP Pharmaceutical Products Inc. Patient Assistance Program can be discontinued or changed at any time without notice at the discretion of TAP.

Lupron
Program Guidelines

General Information

Program Phone Number	(800) 830-1015
Customer Service Hours	8:00 am– 5:30 pm CST
Fax Number	(866) 884-5909
TAP Medical Information Line	(800) 622-2011
Program Address	Tap Pharmaceuticals, Inc. Patient Assistance Program P.O. Box 66586 St. Louis, MO 63166-6586

Physicians must fax or mail a completed application to enroll their patient into the program. Enrollment is valid up to 12 months, depending on the diagnosis of the patient and product requested (See Re-enrollment section). Each re-order is submitted by faxing or mailing a new application with sections 1 and 2 filled out or by the physician phoning in a request (see Re-order section).

Application Requests

Physicians or patients may call to request an application. Applications are faxed back to the physician's office upon request. If requested, applications can be mailed to the patient.

Eligibility

All information provided on the application will be reviewed to determine the status of the application. The appropriate correspondence will be faxed to the physician's office.

- Orders can only be shipped within the United States. Orders cannot be shipped to Puerto Rico or the Virgin Islands.
- The call center is allowed to inform the patients and doctors of the FPL (Federal Poverty Level) requirements for the program if asked.
- Patients must provide their total monthly household net income.
- Patients must not exceed 300% of the FPL based on their total monthly household net income. These guidelines can be found on the Internet.
- Patients must be a United States legal resident. Patients are required to submit their social security number or an ID number for the immigrant Visa.
- Patients are not eligible if they have medical benefits IF injectables are covered (see Medical and Pharmacy Benefits section)

- Patients are not eligible if they have pharmacy benefits IF injectables are covered (see Medical and Pharmacy Benefits section)
- Patient's diagnosis is required. The diagnosis must be an approved FDA indication for the product to be eligible for this program. Physicians for pediatric patients are required to submit copies of the STIM test, bone age, tanner stage documentation to be eligible for the program.
- Medical expenses paid out by the patient towards other medications/medical services will **not** be excluded from their total monthly household net income.
- A Medicaid denial letter is not required to determine enrollment
- Patients are not required to submit financial documentation to be eligible for the program
- A prescription is not required
- TAP does not have a limitation of assets for patients to be eligible for the program.
- Incarcerated patients are not eligible
- Appeals are accepted for denials. Physicians must submit a letter of appeal vial fax or mail.

Medical and Pharmacy Benefits

Urology, Pediatric and Gynecology patients are allowed to have medical or pharmacy benefits through private, commercial or government agencies **IF** injectables are not covered. Also, if Medicare Part B covers the patient they are not eligible.

- If the patient indicates on the application that they are enrolled in private insurance and/or Medicaid AND indicates that injectables are NOT covered by benefits, the patient will be approved.
- If the patient indicates on the application that they are enrolled in private insurance and/or Medicaid AND indicates that injectables ARE covered by benefits, the patient will be denied.

Re-Enrollment

- Urology and Pediatric patients are allowed to re-enroll after their initial 12-month eligibility term has expired. Physicians and patients must complete a new application with updated insurance and income information to re-enroll the patient.
- Endometriosis patients may only enroll for two, 6- month eligibility periods and may not re-enroll once their eligibility has expired (maximum 12-month lifetime enrollment). Physicians and patients must complete a new application with updated insurance and income information for the second, 6-month enrollment period.
- Uterine Fibroid patients may only enroll for one, 3-month eligibility period and may not re-enroll once their eligibility period has expired (maximum 3-month lifetime enrollment).

Rejected Applications

If the submitted application is missing information, the application along with a letter of rejection will be faxed to the physician. The rejection letter will state the reason for rejection. Older applications or obsolete applications will be rejected.

Applications are considered incomplete if they are missing any of the following information:

- Enrolling Physician
- Physician DEA# or state license #
- Physician Address
- Physician Phone #
- Physician Signature
- No product indicated
- Pediatric patient STIM, bone age and tanner stage documentation
- Patient Name
- Patient SS/Green Card #
- Diagnosis
- Number of people in household
- Total monthly household income
- US Residency Indicated
- Patient Medical Insurance Information (all 3 sections) – If patient indicates enrollment in Medicare~~,~~ the patient must indicate if enrolled in Part A and/or Part B~~.~~
- Patient/ legal guardian signature

Denied Applications

If an application is denied, a notification letter of denial and the application will be faxed to the physician. If denied, patients must wait 3 months before re-applying for the program.

Patients will be denied the program for the following reasons:

- Patient is not a legal US Resident.
- Patient must have a valid SS# or ID#.
- Patient's monthly income exceeds the guidelines set by TAP.
- Gynecology, Urology or Pediatric patient has medical and/or pharmacy benefits AND Lupron is covered.
- Patient has Medicare Part B
- Product requested is not being used for a FDA approved indication.

Approved Applications

Once an application is approved, a notification letter of approval will be faxed to the physician.

Product Quantity and Limitations

Patient ICD.9 Code	Patient Diagnosis	Product Strength	Max # Kits per enrollment	Day Supply	Maximum Length of Therapy	Enrollment Period
617.X	Endometriosis	3.75MG	6	30	12 months	Two, 6- month enrollments (12 Months Lifetime)
617.X	Endometriosis	11.25MG	2	90	12 months	Two, 6- month enrollments (12 Months Lifetime)
	Suspected Endometriosis	3.75MG	2	90	12 months	Two, 6- month enrollments (12 Months Lifetime)
	Suspected Endometriosis	11.25MG	2	90	12 months	Two, 6- month enrollments (12 Months Lifetime)
218.9	Uterine Fibroids	3.75MG	3	30	3 months	3 Months Lifetime
218.9	Uterine Fibroids	11.25MG	1	90	3 months	3 Months Lifetime
185, 233.4	Prostate Cancer, Carcinoma of Prostate	7.5MG	12	30	N/A	12 Months (re-enrollment required annually)
185, 233.4	Prostate Cancer, Carcinoma of Prostate	22.5MG	4	90	N/A	12 Months (re-enrollment required annually)
185, 233.4	Prostate Cancer, Carcinoma of Prostate	30MG	3	120	N/A	12 Months (re-enrollment required annually)
259.1	Central Precocious Puberty	7.5MG	12	30	N/A	12 Months (re-enrollment required annually)
259.1	Central Precocious Puberty	11.25MG	12	30	N/A	12 Months (re-enrollment required annually)
259.1	Central Precocious Puberty	7.5MG	12	30	N/A	12 Months (re-enrollment required annually)

Reorders

Enrolling physicians are required to fax or mail a new application or phone in reorders. A physician may reorder for the patient when 2/3 of the duration of the injection has expired. A physician will not be able to reorder if the patient has met the maximum quantity allowed by the diagnosis.

Dosage Changes

If dosage changes are necessary the physician should contact the call center for instructions.

TAP Patient Assistance Point of Contact

R & D Pharmacovigilance administers the Lupron Patient Assistance Program. For help and information regarding this program, call the Call Center at 1-800-622-2011.