Patient Assistance Program
250 Phillips Blvd, Ste 250, Ewing, NJ 08618
1-800-425-3122 Telephone 1-800-685-2577 Fax
Hours of Operation: Monday through Friday, 8:30 AM to 5:30 PM EST

ParaGard® Patient Assistance Program Eligibility Requirements

A ParaGard unit will be provided free of charge to patients who meet program eligibility requirements:

- Patient must be a US resident
- Patient must be 18 years of age or older
- Patient's gross annual household income must be at or below 200% HHS Poverty Guidelines*****
- Patient must provide proof of gross annual household income
  - Financial documentation must be included with the Qualification Form.
  - Proof of income includes copies of both:
    - a) federal tax return (Form 1040 or 1040EZ) for prior tax year, and
    - b) all other recent documents that show income paid to patient (and/or spouse if married), such as: wage and tax statements (W-2 forms), Social Security, Pension, or Railroad Retirement statements (SSA-1099 or similar), Statements of interest, dividends, or other income (1099-INT, 1099, 1099-DIV, or other forms)
- Patient cannot have any private, third-party or government insurance that covers ParaGard in whole or in part, including Medicare, Medicaid, or any state or local programs.

Additional requirements:

- Program Qualification Form must be completed in its entirety by the healthcare professional caring for the patient.
- Both patient and healthcare professional must sign the Qualification Form in the appropriate section
- Patient must sign and submit the Authorization to Disclose Form
- Healthcare professional must have a current valid state license

***** Income criterion is based on Health and Human Services Poverty Guidelines. These guidelines may be revised each new year, usually around February. Website is: http://aspe.hhs.gov/poverty/index.shtml

Please see full prescribing information.

Duramed Pharmaceuticals, Inc.
Subsidiary of Barr Pharmaceuticals, Inc.
Pomona, NY 10970

Duramed Pharmaceuticals, Inc. reserves the right to limit enrollment of patients to the **ParaGard Patient Assistance Program** at any time.

The program administrators reserve the right any time and without notice to modify the application form, modify or discontinue any or all of the program and the related eligibility criteria; or at any time terminate assistance provided by the program.

ParaGard® Patient Assistance Program
250 Phillips Blvd, Ste 250, Ewing, NJ 08618
Phone: 1-800-425-3122 Fax: 1-800-685-2577
www.paragard.com

Qualification Form

NM

PATIENT INFORMATION (Please Print) Patient must be a U.S. resident

First Name: _____ MI: ____ Last Name: _____ Social Security #: _____

Address: _____ Apt # _____

City: _____ State: _____ Zip Code: _____

Date of Birth: (mm/dd/yyyy) _____ (Patient must be 18 years of age or older) Phone: _____

Current gross annual household income: $ _____ Number of household members dependent on income (including patient) _____ Number of children: _____

Patient financial documentation must be included with this application. *Proof of income includes copies of both: a)your federal tax return (Form 1040 or 1040EZ) for prior tax year,* ***and*** *b) All other recent documents that show income paid to you (or your spouse if married), such as: wage and tax statements (W-2 forms), Social Security, Pension, or Railroad Retirement statements (SSA-1099 or similar), Statements of interest, dividends, or other income (1099-INT, 1099, 1099-DIV, or other forms)*

Patient's insurance and prescription coverage (in whole or in part) Check all that apply.

☐ Medicare	☐ Includes Rx	☐ State or Local Government Programs	☐ Includes Rx	☐ Other	☐ Includes Rx
☐ Medicaid	☐ Includes Rx	☐ Private Insurance, HMO or PPO	☐ Includes Rx	Specify Other:	

If insurance includes Rx coverage, name of carrier: _____

☐ Uninsured

☐ **I certify that I do not have insurance coverage either in whole or in part for ParaGard®**

PATIENT'S VERIFICATION AND SIGNATURE

I verify that the information provided in this application is complete and accurate. I understand that completing this form does not ensure that I will qualify for this program. I certify that I do not have private, third-party or government insurance coverage (either in whole or in part) for ParaGard. I understand that the program administrators reserve the right any time and without notice to modify the application form, modify or discontinue any or all of the program and the related eligibility criteria; or terminate assistance provided by the program at any time. I authorize Duramed Pharmaceuticals, Inc. to use the information on this application to process my request and the use of my Social Security number for identification purposes and record keeping.

Patient's Original Signature: _____ Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

HEALTHCARE PROFESSIONAL INFORMATION (Please Print)

First Name: MI: Last Name: Title:

Facility: _____ Office Contact Name: _____

Street: _____ Bldg/Suite/Floor/Room: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____ E-Mail: _____

If this is your first time submitting to ParaGard PAP, ***you must submit a copy*** *of your State License.* State License Number: _____

A ParaGard unit will be shipped directly to the healthcare professional's office address above. A signature is required at time of delivery.

Office hours: _____ Special Delivery Instructions: _____

Rx 1 Unit Product ParaGard® T 380A IUD

HEALTHCARE PROFESSIONAL'S VERIFICATION AND SIGNATURE

I represent that the information contained in this application is complete and accurate to the best of my knowledge. To the best of my knowledge, this patient does not have medical insurance (including Medicare, Medicaid or other public programs), which covers ParaGard either in whole or in part, and the patient meets the income criteria required to qualify for this Patient Assistance Program. No claim may be made to any third party payer (including government payers) for payment of the ParaGard unit provided by this Patient Assistance Program. The ParaGard received for this patient may not be sold or traded, may not be returned for credit, and is not a sample. I understand that the ParaGard Patient Assistance Program has the right to modify or discontinue this program and its eligibility requirements, or to terminate assistance, at any time and without prior notice.

Please indicate that you agree to these terms by signing below. Your signature confirms that there is a need for this patient's prescription for ParaGard®.

HCP's Original Signature: _____ Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

Duramed Pharmaceuticals, Inc. reserves the right to limit enrollment of patients to the ParaGard Patient Assistance Program at any time.

Patient Assistance Program

250 Phillips Blvd, Ste 250, Ewing, NJ 08618
1 – 800 – 425 – 3122 – Phone
1 – 800 – 685 – 2577 – Fax

Patient Authorization to Disclose Protected Health Information

To the Patient: I understand that during the course of my participation in the ParaGard Patient Assistance Program, that personal identifying information provided will be provided to Duramed Pharmaceuticals, Inc. its affiliated companies and subcontractors on a need to know basis for purposes of administering the program. I understand this information may constitute Protected Health Information (PHI) under the privacy rules of the Health Insurance Portability and Accountability Act (HIPAA).

Authorization Statement

I, (Patient's Name) , authorize my prescribing healthcare professional,
(HCP's Name)
(HCP's Address)

caregiver and other sources, as deemed necessary to disclose any personal identifying information to Duramed Pharmaceuticals, Inc., its affiliated companies and subcontractors on a need to know basis for purposes of administering the program for the duration of my participation in the program. I understand that Duramed and its affiliated companies and subcontractors value my privacy. As such, Duramed and its affiliated companies and subcontractors will take reasonable and appropriate measures to protect the information provided by me from inappropriate disclosure and will comply with all applicable state and federal privacy laws.

I further understand that this authorization permits Duramed Pharmaceuticals, Inc., its affiliates and subcontractors to share my personally identifiable information with individuals or entities who are not bound ethically or by any privacy laws and that once in their possession, my personally identifiable information could be used or re-disclosed for any purpose.

I understand that I may revoke this authorization, in writing, at any time by addressing such revocation to my prescribing healthcare professional and/or caregiver and that only a written revocation addressed to such person will constitute an effective withdrawal of my authorization.

Required Signature _____ _____
Signature of patient or legal representative **Date**

If signed by patient's legal representative, complete the following:

Print name of legal representative: _____

Describe representative's authority to act for patient: _____

****

Important:

To the Patient:

Once you have completed and signed this authorization form, please give it to your healthcare professional. Do not send it to the ParaGard Patient Assistance Program.

To the Healthcare Professional:

Retain the original copy of the Patient Authorization to Disclose Protected Health Information for your records. Please return a copy of this signed form along with the completed Qualification application form to the ParaGard Patient Assistance Program, 250 Phillips Blvd, Ste 250, Ewing, NJ 08618, or fax to 1-800-685-2577.

NM

 PPAPPAD October 2008

ParaGard® T 380A
intrauterine copper contraceptive

Brief Summary

(See package brochure for full prescribing information)

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

ParaGard® T 380A Intrauterine Copper Contraceptive should be placed and removed only by healthcare professionals who are experienced with these procedures.

INDICATIONS AND USAGE

ParaGard® is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

CONTRAINDICATIONS

ParaGard® should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard®
10. A previously placed IUD that has not been removed

WARNINGS

1. **Intrauterine Pregnancy**
If intrauterine pregnancy occurs with ParaGard® in place and the string is visible, ParaGard® should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard® is in her uterus (for example, by ultrasound). If ParaGard® is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. **Ectopic Pregnancy**
Women who become pregnant while using ParaGard® should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard® in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard® prevents most pregnancies, women who use ParaGard® have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. **Pelvic Infection**
Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD-user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has *symptoms* of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

4. **Immunocompromise**
Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. **Embedment**
Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. **Perforation**
Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard® promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. **Expulsion**
Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. **Wilson's Disease**
Theoretically, ParaGard® can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. **Information for patients**
Before inserting ParaGard® discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. **Insertion precautions, continuing care, and removal.**
(See **Package Brochure for INSTRUCTIONS FOR USE**.)

3. **Vaginal bleeding**
In the 2 largest clinical trials with ParaGard® (see ADVERSE REACTIONS, Table 2), menstrual changes were the most common medical reason for discontinuation of ParaGard®. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard® because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2 % in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard®. (See **ADVERSE REACTIONS**.)

4. **Vasovagal reactions, including fainting**
Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. **Expulsion following placement after a birth or abortion**
ParaGard® has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard® is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard® can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. **Magnetic resonance imaging (MRI)**
Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard®. One study examined the effect of MRI on the CU-7® Intrauterine Copper Contraceptive and Lippes Loop™ intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard® was subjected to MRI.

7. **Medical diathermy**
Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. **Pregnancy**
ParaGard® is contraindicated during pregnancy. (See CONTRAINDICATIONS and WARNINGS.)

9. **Nursing mothers**
Nursing mothers may use ParaGard®. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. **Pediatric use**
ParaGard® is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in **WARNINGS** and **PRECAUTIONS**. These include:

Intrauterine pregnancy
Septic abortion
Ectopic pregnancy
Pelvic infection
Perforation
Embedment

Table 2 shows discontinuation rates from two clinical studies by adverse event and year.

Table 2. Summary of Rates (No. per 100 Subjects) by Year for Adverse Events Causing Discontinuation

Adverse Event	Year									
	1	2	3	4	5	6	7	8	9	10
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7
Other Medical Event	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3
No. of Women at Start of Year	4932	3149	2018	1121	872	621	563	483	423	325

*Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the Population Council (3,536 subjects) and the World Health Organization (1,396 subjects) trials.

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia
Backache
Dysmenorrhea
Dyspareunia
Expulsion, complete or partial
Leukorrhea
Menstrual flow, prolonged
Menstrual spotting
Pain and cramping
Urticarial allergic skin reaction
Vaginitis

DURAMED PHARMACEUTICALS, INC.
Subsidiary of Barr Pharmaceuticals, Inc.
Pomona, New York 10970
Revised MAY 2006 (v.1)